

Exhibit 8

1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE DISTRICT OF NEW JERSEY
3 CAMDEN VICINAGE

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5

6 IN RE: VALSARTAN, LOSARTAN, MDL No. 2875
7 AND IRBESARTAN PRODUCTS
8 LIABILITY LITIGATION Civil No.
9 19-2875
10 ***** (RBK/JS)

11 THIS DOCUMENT APPLIES TO ALL HON ROBERT B.
12 CASES KUGLER
13 *****

14 - CONFIDENTIAL INFORMATION -
15 SUBJECT TO PROTECTIVE ORDER

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18 Remote Videotaped via Zoom
19 Deposition of MIN LI, Ph.D., commencing at 7:03
20 a.m. China Standard Time, on the 20th of
21 April, 2021, before Maureen O'Connor Pollard,
22 Registered Diplomate Reporter, Realtime
23 Systems Administrator, Certified Shorthand
24 Reporter.

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30 GOLKOW LITIGATION SERVICES
31 877.370.3377 ph | 917.591.5672 fax
32 deps@golkow.com

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| <p>Page 2</p> <p>1 APPEARANCES: ALL PARTIES APPEARED REMOTELY 2 3 MAZIE SLATER KATZ & FREEMAN, LLC 4 BY: ADAM SLATER, ESQ. 5 BY: CHERYL A. CALDERON, ESQ. 6 BY: JULIA S. SLATER, ESQ. 7 BY: CHRISTOPHER GEDDIS, ESQ. 8 103 Eisenhower Parkway 9 Roseland, New Jersey 07068 10 973-228-9898 11 aslater@maziesslater.com 12 ccalderon@maziesslater.com 13 cgeddiss@maziesslater.com 14 Representing the Plaintiffs 15 16 GOLDENBERG LAW, PLLC 17 BY: MARLENE J. GOLDENBERG, ESQ. 18 800 LaSalle Avenue, Suite 2150 19 Minneapolis, Minnesota 55402 20 612-436-5028 21 mjtgoldenberg@goldenberglaw.com 22 Representing the Plaintiffs 23 24 KANNER & WHITELEY, LLC 25 BY: LAYNE HILTON, ESQ. 26 701 Camp Street 27 New Orleans, Louisiana 70130 28 504-524-5777 29 lhilton@kanner-law.com 30 Representing the Plaintiffs 31 32 HOLLIS LAW FIRM 33 BY: IRIS SIMPSON, ESQ. 34 BY: C. BRETT VAUGHN, ESQ. 35 8101 College Boulevard, Suite 260 36 Overland Park, Kansas 66210 37 800-701-3672 38 iris@hollislawfirm.com 39 Representing the Plaintiffs 40</p> | <p>Page 4</p> <p>1 APPEARANCES (Continued): 2 3 GREENBERG TRAURIG LLP 4 BY: KATE M. WITTLAKE, ESQ. 5 4 Embarcadero Center, Suite 3000 6 San Francisco, California 94111 7 415-655-1285 8 wittlakek@gtlaw.com 9 Representing the Defendants Teva 10 Pharmaceutical Industries, Ltd., Teva 11 Pharmaceuticals SA, Inc., Actavis LLC, 12 and Actavis Pharma, Inc.: 13 14 DUANE MORRIS, LLP 15 BY: NATHAN B. REEDER, ESQ. 16 30 South 17th Street 17 Philadelphia, Pennsylvania 19103 18 215-979-1164 19 nbreeder@duanemorris.com 20 Representing the Defendants Zhejiang 21 Huahai Pharmaceutical Co., Ltd., 22 Princeton Pharmaceutical Inc., Huahai 23 U.S., Inc., and Solco Healthcare US, 24 LLC 25 26 DUANE MORRIS, LLP 27 BY: PATRICK C. GALLAGHER, ESQ. 28 1875 NW Corporate Boulevard 29 Boca Raton, Florida 33431 30 561-962-2131 31 pcgallagher@duanemorris.com 32 Representing the Defendants Zhejiang 33 Huahai Pharmaceutical Co., Ltd., 34 Princeton Pharmaceutical Inc., Huahai 35 U.S., Inc., and Solco Healthcare US, 36 LLC 37 38</p> |
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| INDEX | | PAGE | Page 6 | Page 8 |
|---|---------------------------------|--------|--------|--|
| 1 EXAMINATION | | | 1 | DEPOSITION SUPPORT INDEX |
| 2 MIN LI, Ph.D. | | | 2 | ----- |
| 3 BY MR. SLATER | | 10 | 3 | |
| 4 | | | 4 | Direction to Witness Not to Answer |
| 5 | | | 5 | PAGE LINE |
| 6 | | | 6 | None. |
| 7 E X H I B I T S | | | 7 | |
| 8 NO. DESCRIPTION | | PAGE | 8 | Request for Production of Documents |
| 9 ZHP-208 Previously Marked. | FDA Guidance for Industry, | | 9 | PAGE LINE |
| 10 | Draft Guidance..... | 178 | 10 | None. |
| 11 ZHP-213 Previously Marked. | 11/29/18 FDA Warning | | 11 | 35 14 |
| 12 | Letter, Bates ZHP01344159 | | 12 | Stipulations |
| 13 | through 4164..... | 246 | 13 | PAGE LINE |
| 14 ZHP-284 Previously Marked. | E-mail chain, Bates | | 14 | None. |
| 15 | NHP00405021 through 5023..... | 198 | 15 | Questions Marked Highly Confidential |
| 16 ZHP-288 Previously Marked. | E-mail with attachments, | | 16 | PAGE LINE |
| 17 | Bates ZHP00359796 through | | 17 | None. |
| 18 9822..... | 199 | | 18 | |
| 19 ZHP-289 Previously Marked. | Solvias report, Bates | | 19 | |
| 20 | ZHP02135008 through 5025..... | 204 | 20 | |
| 21 ZHP-291 Notice to Take Videotaped | Deposition..... | 12 | 21 | |
| 22 ZHP-292 Min Li, PhD's resume..... | 59 | | 22 | |
| 23 ZHP-293 Min Li's LinkedIn Profile..... | 70 | | 23 | |
| 24 | | | 24 | |
| | | PAGE 7 | Page 9 | |
| 1 ZHP-294 PowerPoint, Center for | Excellence for Modern | | 1 | PROCEEDINGS |
| 2 | Analytical Technologies, | | 2 | |
| 3 | Bates ZHP00404315 through | | 3 | THE VIDEOGRAPHER: We are now |
| 4 | 327..... | 74 | 4 | on the record. |
| 5 ZHP-295 7/27/17 e-mail, Bates | ZHP00190573 and 574..... | 82 | 5 | My name is Judy Diaz, I am a |
| 6 ZHP-296 English translation of | ZHP-295..... | 84 | 6 | legal videographer for Golkow |
| 7 | | | 7 | Litigation Services. |
| 8 ZHP-297 Invention Patient | Application, Bates | | 8 | Today's date is April 20, 2021, |
| 9 | ZHP01812101 through 2109..... | 107 | 9 | and the time is 7:03 a.m. |
| 10 ZHP-298 Chinese translation of | ZHP-297..... | 107 | 10 | This remote video deposition is |
| 11 ZHP-299 Valsartan Patent | Investigation Report, Bates | | 11 | being held in the matter of Valsartan, |
| 12 | ZHP02336567 and ZHP02336682.... | 116 | 12 | Losartan, and Irbesartan Products |
| 13 ZHP-300 Document titled SciFinder, | Bates ZHP02336432 through | | 13 | Liability Litigation MDL. |
| 14 | 6434..... | 121 | 14 | The deponent is Min Li, Ph.D. |
| 15 ZHP-301 12/22/18 e-mail, Bates | ZHP01391682..... | 124 | 15 | All parties to this deposition |
| 16 | | | 16 | are appearing remotely and have agreed |
| 17 ZHP-302 English translation of | ZHP-301..... | 125 | 17 | to the witness being sworn in |
| 18 ZHP-303 Excel spreadsheet, Summary | of CEMAT reports..... | 128 | 18 | remotely. |
| 19 | | | 19 | All counsel will be noted on |
| 20 ZHP-304 English version of ZHP-303.... | 129 | | 20 | the stenographic record. |
| 21 ZHP-305 Study Report of Unknown | Peak in Residual Solvent of | | 21 | The court reporter is Maureen |
| 22 | Valsartan, Bates | | 22 | Pollard, and will now swear in the |
| 23 | ZHP01870977 through 1119..... | 223 | 23 | witness. |
| 24 | | | 24 | /// |

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| <p>1 MIN LI, Ph.D., 2 having been duly remotely sworn, was examined 3 and testified as follows: 4 EXAMINATION 5 BY MR. SLATER: 6 Q. Good evening. 7 A. Good evening. Yeah, I'm here. 8 Actually, it's morning here. 9 Q. Okay. We're here to take your 10 deposition. Do you understand that's the 11 purpose of this proceeding? 12 A. Sure. Yes. 13 Q. Have you ever been deposed 14 before? 15 A. No. 16 Q. This is a sworn proceeding in 17 the United States District Court. 18 Do you understand that you're 19 now under oath and must tell the truth? 20 A. Yes, I understand. 21 Q. If for any reason you are asked 22 a question and don't feel like you either 23 understand it or can answer it truthfully and 24 accurately for any reason based on how the</p> <p>1 question was asked or what was asked, just 2 tell me. 3 A. Sure. 4 Q. It may be that I mispronounce a 5 word or use scientific jargon incorrectly. 6 Whatever the case may be, you can just let me 7 know what's unclear, and I can try to 8 rephrase the question. Okay? 9 A. Okay. Great. 10 Q. During the course of the 11 deposition, there will be objections and 12 discussion between the attorneys. That's 13 normal. That's people preserving the record 14 for future use in the court. 15 It's not something that should 16 throw you off; I just want you to know that 17 might happen, okay? 18 A. Okay. 19 Q. And certainly there's no reason 20 why any objection or statement by any 21 attorney would be any sort of a prompt for 22 you to say anything or not say anything. 23 It's just the attorneys discussing their 24 legal positions on different things.</p> | <p>Page 10</p> <p>1 So certainly that's not 2 something you would ever want to be doing, is 3 taking a cue from an attorney's objection or 4 anything they say. 5 Do you understand that? 6 A. Okay. 7 Q. What is your current title? 8 A. I'm the vice-president for 9 analytical operation for Huahai 10 Pharmaceutical Company, or also known as ZHP, 11 particularly, you know, in this case. 12 MR. SLATER: Let's put up 13 Exhibit 291, please, Cheryll. 14 (Whereupon, Exhibit Number 15 ZHP-291 was marked for 16 identification.) 17 MR. SLATER: Great. Thank you. 18 BY MR. SLATER: 19 Q. On the screen is the notice to 20 take your deposition. Have you seen this 21 document before? 22 A. Yes. Actually, I also have a 23 copy, yes. 24 Q. Oh, you have a copy in front of</p> |
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| <p>1 your attorneys; I think you called it 2 training from your lawyers. 3 Who was it that you spoke with? 4 A. You know, here Patrick, and 5 also Rick, Nason. Mostly, you know, those 6 three. Sometimes, you know, there's other, 7 like Seth. 8 Q. Did you speak to any attorneys 9 in China in preparing for the deposition? 10 A. No. Because I'm a US citizen, 11 I don't think it's legally obligated for me 12 to talk to anybody, you know, or any lawyer, 13 you know, in China. 14 Q. Did anybody tell you that? 15 A. Yeah. I mean, you know, the 16 lady, you know, in the general -- you know, 17 in the president office, you know, she's 18 basically managing this. You know, that's 19 what she told me, because she's being 20 basically, you know, get in touch with, you 21 know, the Chinese lawyer for my Chinese 22 colleagues, because we want to make sure, you 23 know, right, we have to be basically abide 24 by, you know, you know, the Chinese law as</p> | <p>Page 14</p> <p>1 A. I really don't remember. 2 Probably, I would assume most likely her, but 3 I, you know, because it's such a long period, 4 and I really cannot tell, like, who is 5 exactly the first person, to be honest with 6 you. I mean, I don't have photographic, you 7 know, memory. 8 Q. When you say it's been "such a 9 long period," can you estimate how long ago 10 it was when you first spoke with someone 11 about this deposition? 12 A. Maybe six months. I don't 13 know. I mean, it's just a very rough 14 estimate. 15 Q. Could it have been a year ago? 16 A. I mean, if you're talking 17 about, you know, you know, starting 18 collecting, you know, the document, yeah, I 19 would say, yeah, that's about, you know, at 20 least about a year ago, yes. 21 Q. When did you first find out 22 your deposition was going to be taken? 23 A. I think sometime last year, 24 because I -- you know, you know, she told me</p> |
| <p>1 well, because otherwise, you know, if you 2 have any procedural violation, you know, you 3 may get into big trouble. 4 Q. Who did you speak with in the 5 president's office? You said you spoke with 6 a woman about the deposition. Who was that? 7 A. Maggie, yeah. Maggie Kong. 8 Yeah, yeah. 9 Q. Can you spell her name, please? 10 A. Last name is K-O-N-G. She 11 usually goes by her English name, you know, 12 Maggie, but also her Chinese name is 13 Xiaofong, Xiaofong Kong. 14 Q. And when did you speak with her 15 about the deposition? 16 A. That was long time. You know, 17 I think in the very early phase. I don't 18 remember exactly, you know, how long. Maybe, 19 like, for several months. 20 Q. Was that the first time you 21 spoke with anybody about this deposition? 22 A. I don't think so. 23 Q. Who was the first person you 24 ever spoke to about the deposition?</p> | <p>Page 15</p> <p>1 I will be one of the -- you know, the 2 witness, you know, will be, you know, giving 3 the testimony. Sometime last year. 4 Q. So you think it was maybe a 5 year ago? 6 A. I wasn't sure. As I said, I 7 wasn't sure exactly, you know, but sometime 8 last year, okay? 9 Q. Well, right now it's April 19th 10 here in the States, so are we talking last 11 April? Are we talking last summer? Are we 12 talking before April? Do you recall? 13 A. As I said, I don't have 14 accurate recollection. 15 Q. Do you have a calendar that you 16 keep that would show you when you were first 17 notified that you were going to be deposed? 18 A. I don't keep that particular 19 calendar, like particularly when was the 20 first day that I received the notice. 21 Because I -- you know, from my perspective, 22 you know, you know, that's not important. I 23 mean, the important thing is I know what's 24 the date and I need to prepare.</p> |

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| <p>1 Q. I wasn't asking you what was 2 important. I'm just asking you if you 3 remember when it was.</p> <p>4 A. I don't remember exactly date. 5 I told you, you know, a few times already.</p> <p>6 Q. Did you receive an e-mail about 7 this deposition back in the beginning?</p> <p>8 A. Yeah, I think so. Yeah, I 9 received an e-mail. You know, if I go back 10 to my, you know, you know, e-mail, I mean, I 11 may be able to tell you tomorrow, you know. 12 You know, after this session I can, you know, 13 if you really wanted to have that.</p> <p>14 Q. That would be great if we could 15 have an understanding of when you first 16 learned about --</p> <p>17 A. Okay.</p> <p>18 MR. GALLAGHER: Object to the 19 extent that -- we'll take it under 20 advisement. Object to the extent it 21 calls for any privileged information.</p> <p>22 BY MR. SLATER:</p> <p>23 Q. You said the first person you 24 ever spoke to about being deposed was Maggie</p> | <p>Page 18</p> <p>1 And also talk to, like, Peng 2 Dong, you know, you know, Mr. Peng Dong, 3 quite early on during, you know, you know, at 4 the early phase of the preparation because I 5 asked him something about, you know, the 6 early -- you know, during the early stage, 7 you know, you know, how that original, you 8 know, you know, process, you know, was 9 developed, you know, you know, the so-called 10 zinc chloride, you know, process.</p> <p>11 Q. Well, we'll go back through the 12 names and what you spoke to them about, but 13 let's try to get the list of names of people 14 from your company you spoke to. So far we 15 have Maggie Kong and we have Peng Dong. 16 Who else from your company did 17 you speak to with regard to anything 18 connected to the deposition?</p> <p>19 A. I also talked to Qiangming Li, 20 you know, as I said, mostly about logistics, 21 getting into, you know, the hotel, you know, 22 everything. Yeah.</p> <p>23 Q. Who else?</p> <p>24 A. Who else? And also talked to</p> |
| <p>1 Kong, is that correct?</p> <p>2 A. I would say likely.</p> <p>3 Q. Who else in your company have 4 you spoken to about the deposition?</p> <p>5 A. I mean, what do you mean by -- 6 you know, speaking about what?</p> <p>7 Q. Anything having to do with the 8 deposition, either the fact of the 9 deposition, what you were going to testify 10 to, how to conduct yourself, obtaining 11 information to testify. Anything connected 12 to the deposition.</p> <p>13 A. I talked to, you know, people, 14 right? Particularly people who travel, you 15 know, to, you know, you know, to Macao, 16 right?</p> <p>17 I talked to them about 18 logistics, you know, about, you know, the 19 procedural, you know, all the details, you 20 know, the purposes just for me, you know, to 21 be able to get to Macao and to be 22 participate in this, you know, testimony, you 23 know. I just want to make sure, you know, 24 things will be done as arranged, right?</p> | <p>Page 19</p> <p>1 one of the staff under, you know, Qiangming 2 Li and asking about some of the specifics.</p> <p>3 Q. Who was that person?</p> <p>4 A. His name is Jun Wang.</p> <p>5 Q. Who else from your company have 6 you spoken to with regard to the deposition?</p> <p>7 A. I think that's about it.</p> <p>8 Q. You said earlier you'd spoken 9 to people in order to get some background 10 information in order to testify.</p> <p>11 Who were the people that you 12 spoke to to get that background information 13 to be able to testify on the topics you were 14 designated on?</p> <p>15 A. The background -- well, 16 basically when I say "background" is, you 17 know, actually I'm referring to, you know, to 18 that particular topic regarding, you know, 19 that process change, right?</p> <p>20 So with that regard I was 21 talking to, you know, Mr. Peng Dong during 22 the early phase, you know, of the 23 preparation.</p> <p>24 Q. What else did you talk to Peng</p> |

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| <p>1 Dong about besides the process change?</p> <p>2 Anything?</p> <p>3 A. No, that's it.</p> <p>4 Q. What specifically did you</p> <p>5 discuss with Mr. Dong regarding --</p> <p>6 A. I just -- I was asking him, you</p> <p>7 know, who basically was involved, you know,</p> <p>8 in that process change.</p> <p>9 He said he was not clear</p> <p>10 because, you know, he probably was not</p> <p>11 involved, you know, during that process, I</p> <p>12 mean.</p> <p>13 Q. So you spoke to Peng Dong about</p> <p>14 the process change, you asked him who was</p> <p>15 involved, and he said he didn't know because</p> <p>16 he wasn't involved, and that was the</p> <p>17 conversation?</p> <p>18 A. Yeah, pretty much, yeah.</p> <p>19 Basically, you know, I was asking him, like,</p> <p>20 who basically was the original sort of, like,</p> <p>21 you can call, like, inventor or whatever,</p> <p>22 like who developed that process.</p> <p>23 Q. And what did he tell you?</p> <p>24 A. He said, you know, you know,</p> | <p>Page 22</p> <p>1 deeper, you know, because I'm not a, you</p> <p>2 know, a process chemist.</p> <p>3 MR. GALLAGHER: I'm going to</p> <p>4 object to the line as outside the</p> <p>5 scope of the 30(b)(6) topics, but</p> <p>6 certainly --</p> <p>7 MR. SLATER: Patrick, you're</p> <p>8 saying that my questioning about how</p> <p>9 he prepared himself to testify for the</p> <p>10 30(b)(6) topics is outside the scope</p> <p>11 of the 30(b)(6) topics?</p> <p>12 MR. GALLAGHER: No, no.</p> <p>13 MR. SLATER: Because that's</p> <p>14 what I'm doing.</p> <p>15 MR. GALLAGHER: Proceed.</p> <p>16 BY MR. SLATER:</p> <p>17 Q. How long did this discussion</p> <p>18 with Peng Dong take?</p> <p>19 A. Just very briefly over the</p> <p>20 phone, yeah.</p> <p>21 Q. Okay. How long did it take?</p> <p>22 A. Maybe five, ten minutes.</p> <p>23 Q. So let me -- rephrase.</p> <p>24 Did you say you also spoke to</p> |
| <p>1 you know, he didn't know.</p> <p>2 Q. Can you tell me who was the</p> <p>3 inventor of the process change, the zinc</p> <p>4 chloride process change?</p> <p>5 A. Well, the -- you know, from the</p> <p>6 document, right, from the document, you know,</p> <p>7 at least some of the document, I know the</p> <p>8 technology was originated from SynCore, okay,</p> <p>9 which is a subsidiary of Huahai</p> <p>10 Pharmaceutical.</p> <p>11 But I was just asking him who,</p> <p>12 you know, that individual, like specifically</p> <p>13 who that individual was.</p> <p>14 Q. And he didn't know?</p> <p>15 A. He didn't -- yeah, he didn't</p> <p>16 know.</p> <p>17 Q. Did you ask anybody else?</p> <p>18 A. No.</p> <p>19 Q. Did you speak to anybody from</p> <p>20 Syncores?</p> <p>21 A. No.</p> <p>22 Q. Why not?</p> <p>23 A. I mean, for me, you know, I</p> <p>24 mean, there's no need for me to go more</p> | <p>Page 23</p> <p>1 Mr. Qiangming Li?</p> <p>2 A. Yes. About the logistics,</p> <p>3 traveling into Macao.</p> <p>4 Q. Did you talk to Qiangming Li</p> <p>5 about anything substantive about your</p> <p>6 testimony?</p> <p>7 A. No.</p> <p>8 Q. Did you ask him any questions</p> <p>9 about something you might testify about?</p> <p>10 A. No.</p> <p>11 Q. The staff member Jun Wang, when</p> <p>12 did you speak to that person?</p> <p>13 A. Not Jun Wang. It's Jun, yeah.</p> <p>14 J -- Jun Wang or Jun Wang.</p> <p>15 Q. I'll ask it again.</p> <p>16 When did you speak to Jun Wang?</p> <p>17 A. Just a few days, like, let me</p> <p>18 see, just two, three days before I came over</p> <p>19 to Macao, yeah, because I just wanted to try</p> <p>20 to clarify some of the, you know, you know,</p> <p>21 chronology of the events, you know, for some</p> <p>22 of the customers, you know, you know, or</p> <p>23 their discussion.</p> <p>24 Because, you know, he was the</p> |

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| <p style="text-align: right;">Page 26</p> <p>1 main person doing the analytical 2 investigation from the QC side, so I just, 3 you know, tried to ask him some of those, you 4 know, you know, you know, details like, you 5 know, how many customers, you know, you know, 6 like been having this.</p> <p>7 You know, some of those, you 8 know, early on we characterized them as like 9 technical exchange, right, and then later on, 10 you know, it's being formally characterized 11 as a customer complaint.</p> <p>12 Well, basically, you know, 13 talking about, you know, these unknown peaks, 14 you know. Yeah. So I was just trying to, 15 you know, you know, find out who -- like 16 when, you know, like the -- you know, what 17 the, you know, their question, you know, was.</p> <p>18 Q. When you say "the unknown 19 peaks," do you mean the unknown peaks that 20 later were identified as nitrosamine peaks?</p> <p>21 A. No. Actually all of the peaks, 22 all of the peaks, right, after I review, you 23 know, those documents, right, all of the 24 peaks people talking about between Huahai's</p> | <p style="text-align: right;">Page 28</p> <p>1 Q. When you say that it can 2 co-elute with a background peak, are you 3 talking about the toluene peak? 4 A. No. Actually, there was one 5 little peak after the toluene peak. 6 Q. And the little peak after the 7 toluene peak turned out to be the nitrosamine 8 peak, correct? 9 A. Oh, no, no. Actually, that 10 peak -- well, that peak in the background, 11 okay -- it's a little bit complicated. Okay. 12 In the background -- so that peak is also 13 eluted in the blank injection, okay? 14 And then in the sample 15 injection, this peak turns out -- if I 16 remember correctly, this peak turns out to be 17 n-butyl acetate, okay? 18 So that's the peak -- that's 19 the peak, you know, eluting after the toluene 20 peak. Okay. So NDMA would elute on the 21 shoulder, or sometimes may even completely 22 co-elute with this peak. 23 Q. When did you speak to Jun Wang? 24 You said two to three days before you came to</p> |
| <p style="text-align: right;">Page 27</p> <p>1 customer and, yeah, all of those peaks, you 2 know, that discuss that specifically they're 3 not nitrosamine. 4 I mean, obviously, I mean, you 5 know, you know, retrospectively maybe one of 6 the tiny -- you know, now we know, right, 7 nitrosamine, you know, you know, it could 8 co-elute with one of the backgrounds. But 9 that's only, you know, you know, after, you 10 know, the facts, you know, after. 11 And then when you spike, you 12 know, the standard sample or reference sample 13 of the NDMA, you know, with a very high, 14 like, concentration, then you -- you know, 15 retrospectively you can say, hey, you know, 16 the NDMA could co-elute, you know, after, you 17 know -- actually on the shoulder of the one 18 background peaks. 19 But all of the -- you know, all 20 of the peaks, you know, people were talking 21 about, you know, retrospectively we know, you 22 know, they are not NDMA or anything, you 23 know -- you know, any other, you know, 24 nitrosamines.</p> | <p style="text-align: right;">Page 29</p> <p>1 Macao. When was that? 2 A. I came here on the 18th. Yeah. 3 So it would be like, you know, around the 4 16th, yeah. 5 Q. The 16th would have been 6 Friday? 7 A. Yes, is 16 Friday? Let's see. 8 Yeah, it's Friday, yes. 9 Q. How long did you talk to Jun 10 Wang about this deposition? 11 A. It's probably 15, 20 minutes. 12 Q. Did you review any documents to 13 prepare for the deposition? 14 A. Did I review any documents? 15 Yes. 16 Q. What did you review to prepare 17 for the deposition? 18 MR. GALLAGHER: Let me just -- 19 give me a minute, Min. 20 To counsel not to disclose the 21 substance of conversations that you 22 had with attorneys. 23 MR. SLATER: I didn't ask 24 anything about attorneys.</p> |

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| <p style="text-align: right;">Page 30</p> <p>1 THE WITNESS: Okay.</p> <p>2 MR. GALLAGHER: You asked about</p> <p>3 documents he reviewed, which he may</p> <p>4 have done with attorneys, so I'm</p> <p>5 just -- he can answer the question.</p> <p>6 I'm just going to caution him not to</p> <p>7 disclose the substance of</p> <p>8 conversations he had with attorneys.</p> <p>9 Please answer the question.</p> <p>10 A. I mean, there are quite a few</p> <p>11 documents here. Yeah, for example, some of</p> <p>12 the --</p> <p>13 BY MR. SLATER:</p> <p>14 Q. Let me ask it very clearly.</p> <p>15 A. You know, regarding, you know,</p> <p>16 unknown peak investigations. And also like</p> <p>17 ICH documents, you know, and also some of</p> <p>18 our -- like SOPs, and also the deviation</p> <p>19 investigation reports. You know, I mean,</p> <p>20 there's a lot of stuff.</p> <p>21 Q. Were you reading these</p> <p>22 documents for the first time?</p> <p>23 A. No. Many of -- I mean, some of</p> <p>24 those, you know, obviously I read before, you</p> | <p style="text-align: right;">Page 32</p> <p>1 Q. You said "before I came." What</p> <p>2 were you referring to?</p> <p>3 A. Well, the 18th of April, I mean</p> <p>4 this last Sunday, came to Macao.</p> <p>5 Q. So before you came to Macao, I</p> <p>6 wasn't clear, how many times did you say you</p> <p>7 spoke to counsel?</p> <p>8 A. Totally, as I said, like five</p> <p>9 or six times.</p> <p>10 Q. When was the first time you</p> <p>11 spoke to counsel in connection?</p> <p>12 A. As I told you, by rough</p> <p>13 estimation, it probably was like maybe a</p> <p>14 month and a half ago. But as I said, it</p> <p>15 could be two months, you know. But it just</p> <p>16 seemed like a ball park.</p> <p>17 Q. How much time did you spend in</p> <p>18 those meetings with counsel?</p> <p>19 A. Usually I would say like about</p> <p>20 two hours roughly, average.</p> <p>21 Q. Okay. Looking at the</p> <p>22 deposition right now, the deposition</p> <p>23 notice -- rephrase.</p> <p>24 Looking at the deposition</p> |
| <p style="text-align: right;">Page 31</p> <p>1 know, like SOPs, ICH documents, you know.</p> <p>2 But some obviously, you know, that I read,</p> <p>3 you know, the very first time.</p> <p>4 Q. You met with counsel how many</p> <p>5 times to prepare for deposition?</p> <p>6 A. Oh, I think like five, six</p> <p>7 times.</p> <p>8 Q. When is the first time you</p> <p>9 spoke to counsel about the deposition?</p> <p>10 A. I don't recall.</p> <p>11 Q. Give me your best estimate.</p> <p>12 A. Let's say -- I have to think</p> <p>13 about it. It's -- you know, in the beginning</p> <p>14 it was like a weekly training, and then we --</p> <p>15 you know, you know, before I came we skipped</p> <p>16 one, so I don't know how many.</p> <p>17 Let's say -- hypothetically</p> <p>18 let's say six times, right? So the fifth</p> <p>19 time will be like a half-month ago, right?</p> <p>20 So then I have another -- yeah,</p> <p>21 so roughly like one and a half months ago</p> <p>22 starting. But don't hold me accountable, you</p> <p>23 know, if it's a little bit off, you know.</p> <p>24 But as I said, it's in the ball park.</p> | <p style="text-align: right;">Page 33</p> <p>1 notice, let's go to the -- actually, you have</p> <p>2 it in front of you, right?</p> <p>3 A. Yeah.</p> <p>4 Q. On the second-to-last page of</p> <p>5 the deposition notice, there was a request</p> <p>6 for your most recent resume/curriculum vitae</p> <p>7 and your LinkedIn profile.</p> <p>8 A. Uh-huh. I already provided it.</p> <p>9 Q. And those are the most recent</p> <p>10 versions of both?</p> <p>11 A. Yes.</p> <p>12 Q. This also asked for</p> <p>13 the complete production of any relevant</p> <p>14 custodial documents for you, "including those</p> <p>15 maintained on personal computers or</p> <p>16 electronic devices, to the extent not</p> <p>17 produced prior."</p> <p>18 Are you producing any documents</p> <p>19 in connection with the deposition at this</p> <p>20 time?</p> <p>21 A. No.</p> <p>22 Q. You started working with ZHP in</p> <p>23 2014, right?</p> <p>24 A. Yes. September of 2014, yes.</p> |

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| <p>1 Q. Were you given any sort of a 2 computer at that time to do your work for 3 ZHP?</p> <p>4 A. Yes.</p> <p>5 Q. What type of computer were you 6 given when you started?</p> <p>7 A. Originally it's a ThinkPad, 8 Lenovo ThinkPad, but that computer broke 9 down. Now I have a Microsoft, like what, 10 ProBook.</p> <p>11 Q. You said you were given a 12 Lenovo ThinkPad when you started, and then it 13 broke. When did it break?</p> <p>14 A. When did it break. That's a 15 very good question. It broke during -- 16 actually during a trip. I don't remember 17 exactly.</p> <p>18 When did it break. Probably 19 somewhere between 2017 to 2018, but, you 20 know, I don't have an accurate, you know, 21 recollection exactly, like, which year.</p> <p>22 Q. When your computer broke, did 23 you notify your company that you needed a new 24 computer?</p> | <p>Page 34</p> <p>1 in writing, and we'll take it under 2 advisement.</p> <p>3 BY MR. SLATER:</p> <p>4 Q. When you said the computer 5 broke on a trip, what happened to the 6 computer?</p> <p>7 A. It just could not start, so I 8 think eventually it turns out to be, you 9 know, a hard drive failure.</p> <p>10 Q. What happened to the data that 11 was on the computer?</p> <p>12 A. I would say, according to the 13 IT guys -- well, quite a few documents 14 actually became permanently damaged, but the 15 majority of them was able to be restored, 16 yeah.</p> <p>17 Q. You said documents were 18 permanently damaged?</p> <p>19 A. Some of the documents, yeah, 20 because of the hardware, you know, failure.</p> <p>21 Q. What types of documents were 22 permanently damaged?</p> <p>23 A. Well, it's -- you know, there's 24 different kinds.</p> |
| <p>1 A. Oh, yeah, mm-hmm.</p> <p>2 Q. Who did you notify?</p> <p>3 A. IT.</p> <p>4 Q. And they got you a new 5 computer?</p> <p>6 A. Yes.</p> <p>7 Q. There would be a record within 8 the company of you asking for a new computer 9 and getting that computer. I assume 10 something like that gets documented, right?</p> <p>11 A. Oh, sure, sure, uh-uh.</p> <p>12 Q. So if we need to know when your 13 computer broke and when you got your new 14 computer, the company should be able to 15 provide that information, right?</p> <p>16 A. Yeah. If I ask, they should be 17 able to provide, yes.</p> <p>18 MR. SLATER: Counsel is going 19 to ask me to send an e-mail or 20 something after the deposition to 21 confirm the request, but that's going 22 to be another one of the things we're 23 going to request.</p> <p>24 MR. GALLAGHER: Please put it</p> | <p>Page 35</p> <p>1 Q. Well, tell me, please, which 2 ones?</p> <p>3 A. Like some of those, like, 4 research papers, you know, some of those 5 research, you know, you know, investigation 6 report. And even, you know, some personal, 7 you know, like pictures.</p> <p>8 Q. Was your computer backed up 9 periodically?</p> <p>10 A. What do you mean, "backed up"?</p> <p>11 Like backed up to, like, an external drive?</p> <p>12 Q. I mean backed up so that the 13 data was held in a separate location so that 14 if your computer stopped working, the data 15 wouldn't be lost.</p> <p>16 A. I -- you know, I didn't do 17 that.</p> <p>18 Q. Is there any protocol in your 19 company to back up computers periodically?</p> <p>20 A. Well, for important documents, 21 you know, you know, the company have archive, 22 so I don't need to, you know, you know, to 23 archive like, you know, by myself.</p> <p>24 Q. How about your e-mails? Were</p> |

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| <p>Page 38</p> <p>1 any of your e-mails lost when your computer 2 broke?</p> <p>3 A. No. E-mail, you know, it's 4 always there, e-mail, you know, because it's 5 always in the server.</p> <p>6 That's, you know, that's what 7 the IT -- you know, at least, you know, it 8 will be preserved according to the company 9 policy, you know, for as long as the company 10 policy, you know, you know, would allow.</p> <p>11 Q. What does the company policy 12 require?</p> <p>13 A. I don't have the specifics.</p> <p>14 Q. You've been there since 2014. 15 Is it your understanding that all the e-mails 16 you've sent or received have been backed up 17 or held on a server?</p> <p>18 A. As I said, yeah, I mean, as 19 long as, you know, you know, the company, you 20 know, policy says, you know, how long it will 21 keep, you know, in company server, it will be 22 there. You know, so that regardless, you 23 know, my personal computer's failure, it will 24 be there.</p> | <p>Page 40</p> <p>1 broke, if you can recall. Otherwise we're 2 obviously going to make our request, but it 3 might help.</p> <p>4 Did it occur in -- you said -- 5 well, rephrase.</p> <p>6 With regard to when your 7 computer broke, was that in 2017, or was that 8 in 2018?</p> <p>9 A. As I said, just around that 10 period. I need to -- I need to -- you know, 11 as I said, I'll talk to my IT guys, you know, 12 you know. They will have the record, right, 13 when the replacement happened.</p> <p>14 Q. When you -- rephrase.</p> <p>15 When your Lenovo ThinkPad 16 broke, did you say that you got a Microsoft 17 ProBook --</p> <p>18 A. Yes.</p> <p>19 Q. -- as your new computer?</p> <p>20 A. Yes.</p> <p>21 Q. And that's another laptop?</p> <p>22 A. Yes.</p> <p>23 Q. Is that the same computer, the 24 one you use today?</p> |
| <p>Page 39</p> <p>1 Q. Has there ever been a time 2 since your computer broke where you realized 3 that a document or any data was lost and you 4 couldn't retrieve it, couldn't find it?</p> <p>5 A. No. I always be able to 6 retrieve, you know, from either my e-mail or 7 from, you know, you know, company's archive, 8 or from my colleagues, you know.</p> <p>9 Q. The ThinkPad, is that a desktop 10 or is that a laptop or something else?</p> <p>11 A. Laptop. Nobody use desktop 12 anymore, as far as I know, I mean, you know, 13 for personal use.</p> <p>14 Q. Well, in your work at ZHP, have 15 you had a desktop computer in addition to the 16 laptop?</p> <p>17 A. No.</p> <p>18 Q. Never had a desktop computer?</p> <p>19 A. I think it's totally obsolete 20 for the purpose, you know, you know, people 21 doing office work. I mean, at least for me, 22 I mean.</p> <p>23 Q. I'd like to be a little more 24 precise on the timing of when your computer</p> | <p>Page 41</p> <p>1 A. Yes.</p> <p>2 Q. So --</p> <p>3 A. Well, no. I'm sorry, no. Hold 4 on, hold on. This is -- no. This is the 5 company's -- you know, you know, the solely 6 dedicated computer, you know, right? What 7 we're talking about right now, okay?</p> <p>8 What I'm saying is, you know, 9 you know, the PC or the laptop I'm using for 10 my business, right, or company business, 11 yeah, is a Microsoft, you know, ProBook, 12 okay?</p> <p>13 Q. During the time you've worked 14 at ZHP, have you also owned other computers 15 for personal use, other than the Lenovo 16 ThinkPad and the Microsoft ProBook?</p> <p>17 A. No.</p> <p>18 Q. Did you use the ThinkPad and 19 the ProBook -- rephrase.</p> <p>20 Did you use the Lenovo ThinkPad 21 not only for company business, but also for 22 personal e-mail?</p> <p>23 A. No, I don't think so. I mean, 24 only maybe for -- let me see. Did I -- for</p> |

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| <p>1 personal -- I cannot guarantee, like, I 2 haven't, like, receive a single, like, a 3 personal e-mail. But I can say usually I 4 don't use that for, you know, you know, for 5 personal e-mails, okay.</p> <p>6 Q. What computer -- during the 7 time -- rephrase.</p> <p>8 During the time you had the 9 Lenovo ThinkPad, what computer did you use 10 for your personal e-mails?</p> <p>11 A. Well, the personal e-mail -- 12 let's see. The personal e-mail -- well, I 13 used the personal e-mail, you know, through 14 the web, right, to access my personal e-mail. 15 I mean is that, is -- to me, 16 you know, you know, I wasn't sure that 17 constitutes as the personal use of the 18 Microsoft, you know, you know, you know, like 19 the ProBook.</p> <p>20 Q. Let's try to take this one step 21 at a time.</p> <p>22 When you had the Lenovo 23 ThinkPad, you had a ZHP e-mail address, 24 right?</p> | <p>Page 42</p> <p>1 try to send an e-mail to you to your work 2 e-mail, and because "Min Li" is in your 3 e-mail address, it would come to your 4 personal e-mail?</p> <p>5 A. No, no, no, no. What I'm just 6 trying to say is sometimes if I, you know, 7 you know, try to, like -- you know, sometimes 8 when I send an e-mail I, you know, also maybe 9 want to cc myself.</p> <p>10 And so when I type, you know, 11 my company's, you know, you know, e-mail 12 address, you know, my personal e-mail 13 address, you know, sometimes may accidentally 14 be typed in, you know.</p> <p>15 Q. On the Microsoft ProBook, have 16 you used your personal e-mail?</p> <p>17 A. I also, as I said, access my 18 personal e-mail accounts from time to time. 19 You know, that's pretty much, you know, you 20 can say that I use, you know, that computer 21 for personal use.</p> <p>22 Q. Did you use your personal 23 e-mail on the Microsoft ProBook for business 24 e-mails?</p> |
| <p>1 A. Yes, uh-huh.</p> <p>2 Q. Did you also have a personal 3 e-mail address not related to your work?</p> <p>4 A. Yes, I have a personal e-mail 5 address.</p> <p>6 Q. Did you use that personal 7 e-mail through the Lenovo ThinkPad?</p> <p>8 A. Yes. Sometimes, yes.</p> <p>9 Q. Did you ever use the personal 10 e-mail for business?</p> <p>11 A. I don't think so. There may be 12 very -- maybe, you know, very few occasions, 13 right, one or twice, somehow, you know, some 14 of the e-mail, you know, may just get crossed 15 over.</p> <p>16 You know, because sometimes 17 when you type, you know, you know, the e-mail 18 address, you know, you know, some of these 19 will automatically show up, because my 20 personal e-mail address has some parts of the 21 e-mail address similar to my company e-mail 22 address; for example, like the words "Min 23 Li."</p> <p>24 Q. You're saying somebody could</p> | <p>Page 43</p> <p>1 A. No.</p> <p>2 Q. Do you know if either of your 3 computers was taken into the control of 4 either IT or your lawyers to be searched in 5 order to pull off documents in connection 6 with this litigation?</p> <p>7 A. My Microsoft ProBook, yes, was 8 taken into, yeah, that purpose, yes.</p> <p>9 Q. When?</p> <p>10 A. They have gone through, yeah, 11 my personal ProBook, yes.</p> <p>12 Q. When?</p> <p>13 A. I think sometime last year.</p> <p>14 Again, you know, I have so many things 15 ongoing, you know, I don't remember exactly.</p> <p>16 Yeah. It should be sometime last year.</p> <p>17 Q. Sometime in 2020?</p> <p>18 A. It looks like. But again, you 19 know, like I said, I need to, you know, find 20 out. If you really wanted that exactly date, 21 I think -- you know, or exactly period, I can 22 find out for you.</p> <p>23 Q. Well, I want your best 24 recollection right now. We may request that</p> |

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| <p>1 also. But what's your best recollection, 2 that your computer was taken in order to take 3 documents off it for this litigation in 2020?</p> <p>4 A. Yeah, I think it should be 5 sometime last year.</p> <p>6 Q. Who was it that did that? Who 7 approached you?</p> <p>8 A. Who approached me.</p> <p>9 Again, this whole activity from 10 Huahai or ZHP's perspective, it was 11 coordinated, again, by Maggie Kong.</p> <p>12 Q. So if Maggie Kong keeps good 13 records, she probably knows when everybody 14 was first told about their depositions and 15 when people were told to bring their 16 computers in to be swept?</p> <p>17 MR. GALLAGHER: Sorry. I'm 18 going to object to the extent you're 19 asking for information that would 20 constitute attorney/client privileged 21 information.</p> <p>22 MR. SLATER: How would that be 23 privileged? I'm asking this witness 24 about another person he works with,</p> | <p>Page 46</p> <p>1 terms of your personal e-mail, what do you 2 have, a Yahoo and a Hotmail address? You use 3 both of those?</p> <p>4 A. I just have a Yahoo as my, you 5 know, active, you know, you know, e-mail. 6 I mean, you know, you know, 7 from years ago may have some other, you know, 8 but those, you know, essentially they are 9 that e-mail, I mean, right? Like many years 10 ago I may have like an AT&T, you know, 11 e-mail, but only -- I would say only, you 12 know, live personal e-mail is my Yahoo 13 e-mail.</p> <p>14 Q. And that would be 15 minli88@yahoo.com?</p> <p>16 A. Yes.</p> <p>17 Q. From 2014 to now, is that the 18 only e-mail address that you've used for your 19 personal e-mail?</p> <p>20 A. Yes.</p> <p>21 Q. Do you also have a smartphone 22 of some type that you use for work?</p> <p>23 A. I have my personal phone.</p> <p>24 Q. What type of phone is that?</p> |
| <p>1 who is not a lawyer.</p> <p>2 MR. GALLAGHER: To the extent 3 there was attorney/client privileged 4 information in those discussions, I 5 caution him not to disclose that.</p> <p>6 BY MR. SLATER:</p> <p>7 Q. Did you ever use your personal 8 e-mail to talk to anybody -- well, rephrase.</p> <p>9 Do you know if your personal 10 e-mail was collected -- well, rephrase.</p> <p>11 Do you know if your personal 12 e-mail was reviewed to see if work e-mails 13 were on your personal e-mail?</p> <p>14 A. I'm sorry, it's -- could you 15 rephrase?</p> <p>16 Q. Sure.</p> <p>17 Do you know whether any e-mails 18 on your personal e-mail that related to your 19 work at ZHP were pulled off the computer and 20 provided to us?</p> <p>21 A. I don't know, because I 22 don't -- I don't know what being pulled off. 23 I have no idea.</p> <p>24 Q. And just so I understand, in</p> | <p>Page 47</p> <p>1 A. It's a Huawei smartphone.</p> <p>2 Q. Can you spell that for me, 3 please?</p> <p>4 A. Huawei, H-U-A-W-E-I. Huawei is 5 the leading smartphone company in China.</p> <p>6 Q. How long have you had the 7 Huawei phone?</p> <p>8 A. I have my current phone since 9 last year.</p> <p>10 Q. What did you have before last 11 year?</p> <p>12 A. What I had before last year, I 13 had another Huawei, but that one had some 14 issue, so I switched to the current one.</p> <p>15 Q. What was the issue with that 16 phone?</p> <p>17 A. The -- it's quite a funny -- 18 the -- you know, you know, the screen pops 19 off. It's not completely pops off, but it 20 just -- you know, I never see something like 21 this before. You know, you know, the screen, 22 the center of the screen, it just swells. 23 And it's still usable, you know, but it's 24 just -- it feels like it can break down any</p> |

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| <p style="text-align: right;">Page 50</p> <p>1 time, so, yeah, so I just switched to another 2 one. Yeah.</p> <p>3 Q. How long did you have that 4 phone for, the swelling phone?</p> <p>5 A. The swelling phone, maybe two, 6 three years.</p> <p>7 Q. What did you have before that?</p> <p>8 A. Before that I had a Samsung 9 smartphone.</p> <p>10 Q. Was the Samsung phone the one 11 you were using as of 2014 when you joined 12 ZHP?</p> <p>13 A. That was, yes.</p> <p>14 Q. What happened to the Samsung 15 phone?</p> <p>16 A. That phone was -- initially it 17 had some battery problem, you know, 18 essentially it was very difficult or even 19 sometimes even impossible to charge.</p> <p>20 Sometimes, you know, when the 21 battery completely dead and you may be able 22 to recharge a little bit, but then eventually 23 to the point it become completely, you know, 24 you know, you cannot charge, so it's just</p> | <p style="text-align: right;">Page 52</p> <p>1 A. How long I get that phone. 2 That's a good question. 3 That should be -- let's see. I 4 would say probably end of 2013, something 5 like that.</p> <p>6 Q. So the Samsung phone that you 7 have for your phone calls and phone messages 8 you had when you joined ZHP?</p> <p>9 A. But at the same time I, you 10 know, I bought, you know, the other -- well, 11 actually, let's see.</p> <p>12 I used another Samsung phone, 13 you know, you know, turned that into, you 14 know, you know -- yeah, I don't remember, you 15 know, the other Samsung phone that I 16 either -- that I bought in China or that I 17 bought in the US.</p> <p>18 But anyhow, you know, I was 19 having two Samsung phones, okay. One is, as 20 I said, that I still use today, but mostly 21 for phone calls or messages to/from United 22 States, okay.</p> <p>23 The other phone, as I said, I 24 don't remember either that I bought it in the</p> |
| <p style="text-align: right;">Page 51</p> <p>1 dead.</p> <p>2 Q. Did you ever have a different 3 phone that you used in the United States 4 versus the phone you used in China?</p> <p>5 A. I have a phone that I use, 6 yeah, in the US.</p> <p>7 Q. Which phone is that?</p> <p>8 A. It's another Samsung.</p> <p>9 Q. That's the phone you have 10 currently?</p> <p>11 A. Currently I have two phones.</p> <p>12 One, you know, you know, I mostly for, you 13 know, for the phone calls, you know, or 14 sometimes for the phone messages, you know, 15 receiving from the United States.</p> <p>16 And, you know, you know, for 17 everything else, you know, that I use my 18 China-based phone, because that's the best -- 19 that's the best way, you know, you have to 20 deal with.</p> <p>21 Q. So the Samsung phone you 22 currently have that you use for phone calls 23 and phone messages, how long have you had 24 that phone?</p> | <p style="text-align: right;">Page 53</p> <p>1 US or bought it in China. But I used the 2 other one -- you know, during, you know, the 3 period that I joined ZHP, I used the other 4 one as my personal phone in China.</p> <p>5 Q. The Samsung phone that you 6 currently have, am I correct that that was 7 the phone that you were using back when you 8 joined ZHP in 2014, the Samsung phone?</p> <p>9 A. That phone was also -- yeah, 10 that phone was also there, yeah. I mean, 11 that phone, fortunately, is still working. 12 Maybe -- you know, maybe I -- you know, you 13 know, maybe the reason it's still working is 14 that I didn't use that much, you know what 15 I'm saying? It's only for, you know, you 16 know, for checking, you know, sometimes for 17 checking the phone messages, you know, 18 sending, you know, you know, phone messages.</p> <p>19 Q. How about sending text messages 20 and receiving text messages?</p> <p>21 A. Oh, yeah, yeah. When I say in 22 sending phone messages, what I mean is 23 actually mostly for sending text messages.</p> <p>24 Q. And those text messages would</p> |

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| 1 relate to work and for personal? 2 A. No, no. Mostly personally. 3 Q. Did you ever send text messages 4 on your Samsung phone that you still have 5 related to work? 6 A. No. 7 Q. Not once? 8 A. No. 9 Q. Did you ever send text messages 10 on any other phone related to work? 11 A. No. I don't like, you know, 12 text messages. 13 Q. Well, you had three different 14 phones for work purposes. Did you ever send 15 text messages related to work on any of those 16 three phones? 17 A. No. 18 Q. Do you know if those phones, if 19 any of your -- rephrase. 20 Do you know if any of your 21 phones were taken by your company so that the 22 information on the phones could be downloaded 23 and then reviewed for production to us as 24 part of the litigation? Did they take your | Page 54 1 A. How long. For quite long. 2 Q. Do you use WeChat for work 3 purposes? 4 A. No. 5 Q. Never? 6 A. Never. I mean, if you -- 7 sometimes, you know, we use WeChat to do 8 the -- sort of like, you know, like phone 9 conversations. I don't know if you consider 10 that's, you know, you know, for work 11 purposes. You know, that will be, you know, 12 the only, you know, only way. 13 MR. SLATER: Cheryll, you can 14 take down the dep notice. That's 15 fine. 16 Q. I don't understand, 17 respectfully, what you just said, so I'll ask 18 it again. 19 Have you ever used WeChat for 20 purposes of your work for ZHP? 21 A. As I said, you know, sometimes 22 we use WeChat sort of like as a -- you know, 23 use that as a phone function. 24 Q. Okay. |
| Page 55 1 phone or phones? 2 A. Did they take my phones. I 3 don't think so. I don't remember. I don't 4 remember if they did that. 5 Q. Did anybody ever tell you at 6 any point that you needed to save your 7 documents and information and not delete 8 anything because of this litigation? 9 A. Oh, yes, mm-hmm. 10 Q. When was that? 11 A. The very first time, it must be 12 two, three years ago, I think. 13 Q. How did you -- 14 A. But again -- 15 Q. Was it someone who spoke to 16 you, or did you get something in writing? 17 A. Somebody sending through the 18 e-mail. Yeah, I think it should be someone, 19 you know, of, you know, Maggie Kong's staff, 20 you know, one of her staff. 21 Q. Do you ever use WeChat? 22 A. Yes. 23 Q. How long have you been using 24 WeChat? | Page 55 1 A. So if you consider that that's, 2 you know, you know, as work related, that 3 would be the only -- you know, only occasion. 4 Q. How often does that happen? Do 5 you do that all the time or -- 6 A. It happens -- I wouldn't say 7 all the times, but it happens from time to 8 time, yeah. Because, you know, you know, 9 sometimes, you know, you know, the other, you 10 know, colleague, maybe they're not 11 accessible, only through the WIFI, you know. 12 So during that circumstances, you know, 13 WeChat, you know, may be, you know, the most 14 effective way, you know, just to talk to 15 them. 16 Q. Do you ever use the 17 videoconferencing WeChat as part of your 18 work? 19 A. No. 20 Q. You never have? 21 A. Never. I don't like the video 22 function. 23 Q. Do you use videoconferencing in 24 any other mode or from any other application |

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| <p>1 for your work?</p> <p>2 A. For other. I don't -- usually</p> <p>3 we just have teleconference, yeah, because,</p> <p>4 you know, using video function, it takes a</p> <p>5 lot of memory, you know, slow down the</p> <p>6 effectiveness of the communications.</p> <p>7 Q. My question is this. Have you</p> <p>8 used videoconferencing as part of your work?</p> <p>9 A. As I said, I don't recall it.</p> <p>10 You know, we -- as I said, we usually just,</p> <p>11 you know, do the audio conference.</p> <p>12 Q. You said usually you do. Does</p> <p>13 that mean sometimes you do videoconference?</p> <p>14 A. Well, because I don't remember,</p> <p>15 you know what I'm saying? There may be</p> <p>16 some -- maybe there's one time, you know,</p> <p>17 someone insisted for whatever the reason.</p> <p>18 But I just don't recall, okay?</p> <p>19 Q. Do you share documents over</p> <p>20 WeChat?</p> <p>21 A. No.</p> <p>22 Q. Have you ever for work?</p> <p>23 A. No, not for work. At least for</p> <p>24 me.</p> | <p>Page 58</p> <p>1 Exhibit 292. Is that your current resume,</p> <p>2 CV?</p> <p>3 A. Yeah, mm-hmm.</p> <p>4 Q. Is it accurate?</p> <p>5 A. Yeah, it is accurate.</p> <p>6 Q. I want to ask you a little bit</p> <p>7 about your work before you joined ZHP.</p> <p>8 According to the document, you</p> <p>9 were employed by Merck & Company before you</p> <p>10 joined ZHP, is that correct?</p> <p>11 A. Mm-hmm, yes.</p> <p>12 Q. What was the work did you at</p> <p>13 Merck?</p> <p>14 A. As I described, you know, I</p> <p>15 think, quite clearly in my summary -- yeah,</p> <p>16 can you go down a little bit? -- everything</p> <p>17 basically is pretty much in there.</p> <p>18 MR. SLATER: Go all the way</p> <p>19 down, please.</p> <p>20 A. I actually worked, you know,</p> <p>21 you know, for Merck twice, right, first</p> <p>22 starting from 1998 through 2005, and then</p> <p>23 2005 to -- you know, I switched to</p> <p>24 Schering-Plough. And by the end of 2009,</p> |
| <p>1 Q. Do you know if your</p> <p>2 conversations on WeChat have been recorded?</p> <p>3 A. I don't know. I mean, like, I</p> <p>4 don't notice there's any recording function</p> <p>5 imbedded, like, in WeChat.</p> <p>6 As far as I know, you know, I</p> <p>7 never recorded any conversations, you know,</p> <p>8 but from the other side, whether they record</p> <p>9 or not, I have no idea.</p> <p>10 Q. So you wouldn't, for example,</p> <p>11 be posting documents on WeChat? Coming back</p> <p>12 to that again. I just want to be clear.</p> <p>13 Let me ask it more clearly.</p> <p>14 Have you ever posted documents or shared</p> <p>15 documents on WeChat?</p> <p>16 A. No.</p> <p>17 MR. SLATER: Let's go to the</p> <p>18 Exhibit 292, I guess it will be, the</p> <p>19 resume, please.</p> <p>20 (Whereupon, Exhibit Number</p> <p>21 ZHP-292 was marked for</p> <p>22 identification.)</p> <p>23 BY MR. SLATER:</p> <p>24 Q. So on the screen is</p> | <p>Page 59</p> <p>1 Schering-Plough was acquired by Merck, so</p> <p>2 essentially, or effectively, I went back to</p> <p>3 Merck.</p> <p>4 Could you enlarge, you know,</p> <p>5 the text a little bit? Yeah.</p> <p>6 Yeah, basically, you know, you</p> <p>7 know, I -- when I was at Merck or</p> <p>8 Schering-Plough or after, you know, after the</p> <p>9 merger, I have a group of scientists that,</p> <p>10 you know -- you know, working in my teams.</p> <p>11 We, you know, pretty much as I</p> <p>12 said, you know, do the atypical --</p> <p>13 manufacturing atypical and all of the</p> <p>14 scientific investigations, analytical method</p> <p>15 development, validation, manufacturing</p> <p>16 process, you know, improvement.</p> <p>17 And, you know, the main focus</p> <p>18 was to do the drug degradation mechanism</p> <p>19 studies and also elucidation of the</p> <p>20 structures of drug degradation products,</p> <p>21 utilizing various LC-MS.</p> <p>22 As I listed here Thermo</p> <p>23 LTQ/Orbitrap, you know, Waters MALDI-TOF, and</p> <p>24 Waters Q-Tof, you know, these are all the</p> |

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| <p style="text-align: right;">Page 62</p> <p>1 different, you know, types of, you know, LC, 2 you know, liquid chromatography, mass 3 spectrometry instrument utilized for, you 4 know, impurity, structure elucidation 5 purposes.</p> <p>6 Q. Did you ever --</p> <p>7 A. I -- I'm sorry, go ahead.</p> <p>8 Q. Did you ever -- rephrase.</p> <p>9 Did you ever have any 10 involvement with Merck's losartan 11 formulations?</p> <p>12 A. No.</p> <p>13 Q. You mentioned -- well, 14 rephrase. I want to ask you about a few 15 things in your resume, some of the 16 terminology.</p> <p>17 One of things you say about 18 your time at Merck is that your laboratory 19 was "very well equipped with state-of-the-art 20 analytical instruments including 9 mass 21 spectrometers of different capabilities."</p> <p>22 A. Right.</p> <p>23 Q. During what time period did you 24 have that state-of-the-art --</p> | <p style="text-align: right;">Page 64</p> <p>1 So essentially, you know, a 2 drug molecule at the time, it will, you know, 3 disintegrate, you know, become somebody else. 4 So we need to identify, you know, those 5 unknown impurities and, you know, to know, 6 you know, what they are, and in order to 7 better control them or to understand how they 8 would form, why, you know, they would form.</p> <p>9 Q. Would these studies be 10 performed as part of a risk assessment before 11 the manufacturing process or during the 12 manufacturing process?</p> <p>13 A. No, no. Actually, when I was 14 at the Merck, also at Schering-Plough, my 15 team was supporting commercialized products, 16 okay?</p> <p>17 So all of the events, they 18 happened many years after these products were 19 launched. Even for the commercial product 20 they were on the market for 30, 40 years.</p> <p>21 Over time was the improvement 22 of analytical methods and also the 23 improvement of the -- you know, the 24 sensitivity of the methods, new impurity, you</p> |
| <p style="text-align: right;">Page 63</p> <p>1 A. That was mostly study from 2 2005, and that was the time that I joined 3 Schering-Plough.</p> <p>4 So since my joining, I start 5 to, you know, establish and also was 6 expanding my, you know, my team.</p> <p>7 So eventually, I think two to 8 three years into that time, like I would say 9 around, you know, maybe 2008, I have these 10 full set of, you know, equipments.</p> <p>11 Yeah, I would say, yeah, 12 because 2009 we already -- end of 2009 we 13 already acquired by Merck. Yeah, so it's 14 somewhere around 2008, the instrument 15 capability of my team reached to -- you know, 16 essentially to, you know, to a peak.</p> <p>17 Q. You mentioned drug degradation 18 studies. What is a drug degradation study?</p> <p>19 A. Well, anything well decomposed 20 over time, you know, it's -- the difference 21 is just, you know, to the extent. Some are 22 very stable, but still they may decompose, 23 you know, a little bit. Some will decompose 24 more obviously than the others, right?</p> | <p style="text-align: right;">Page 65</p> <p>1 know, will emerge or will -- you know, they 2 actually sometimes, in some, you know, cases, 3 you know, those impurities, they've always 4 been there; it's just because, you know, the 5 old methodology was not sensitive or specific 6 enough. You know, they were just there, you 7 know, undetected.</p> <p>8 But then one day, you know, 9 sometimes by a rather, you know, 10 coincidental, you know, you know, factors, 11 you know, they become known. So, yeah, so 12 then my team quite often will be called in to 13 do the investigation.</p> <p>14 Q. Do you recall any specific 15 examples of those decomposing chemicals that 16 Merck had found, where it had been happening 17 for a long time and your company didn't know 18 it?</p> <p>19 A. Oh, yeah. Oh, yeah. I can 20 give you one example. For that example we 21 also published a paper, actually. Yeah.</p> <p>22 So there was one product, it 23 containing a, you know, drug substance, or 24 also we can call it active pharmaceutical</p> |

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| <p>1 ingredients.</p> <p>2 You know, that API was</p> <p>3 betamethasone dipropionate, okay, which is a</p> <p>4 steroids, you know, anti-inflammatory, you</p> <p>5 know, you know, steroids. It's a lotion</p> <p>6 product, okay, as far as I can remember.</p> <p>7 And the reason that I can</p> <p>8 remember is because that was the -- that was</p> <p>9 the first, you know, significant</p> <p>10 investigation my team was working on, right?</p> <p>11 So there was, you know, a known</p> <p>12 degradation product, okay? So that</p> <p>13 degradation product was a hydrolytic, you</p> <p>14 know, degradation product. It's called</p> <p>15 21-monopropionate of betamethasone.</p> <p>16 And at this degradation</p> <p>17 product -- I'm sorry.</p> <p>18 This degradation product has</p> <p>19 always been known. You know, they eluted at</p> <p>20 one particular place, right? And then all of</p> <p>21 a sudden there was one day in the QC lab, it</p> <p>22 just happened to be maybe that one particular</p> <p>23 column has slightly better resolution than</p> <p>24 the others, right, and that peak is splitted</p> | <p>1 20, 30 years already.</p> <p>2 So based upon the structure</p> <p>3 that we determined, then we start to search</p> <p>4 the literature, right? And then based upon</p> <p>5 the literature, you know, you know, this</p> <p>6 particular degradant, you know -- basically</p> <p>7 historical, you know, literature provided</p> <p>8 some clue as to how, you know, this</p> <p>9 degradation could come, right, or, you know,</p> <p>10 could happen.</p> <p>11 But based upon, you know, you</p> <p>12 know, larger reasoning, we figured that</p> <p>13 this -- you know, the literature results</p> <p>14 cannot completely explain, you know, you</p> <p>15 know, the phenomenon that we see.</p> <p>16 So based upon that and also,</p> <p>17 you know, and also based upon the stability</p> <p>18 results, we finally able to -- you know, to</p> <p>19 find out a new or a novel degradation</p> <p>20 mechanism from betamethasone dipropionate.</p> <p>21 So we also, you know,</p> <p>22 provide -- actually published another paper</p> <p>23 specifically describing the -- you know, you</p> <p>24 know, this newly formed, you know,</p> |
| <p>1 into two peaks, okay? It just barely, you</p> <p>2 know, you know, split it, right?</p> <p>3 And according to the SOP of the</p> <p>4 QC lab, once you have the splitting on a --</p> <p>5 you know, you know, on a particular peak,</p> <p>6 right, you have to do investigation, right?</p> <p>7 Because according to the SOP, you have to do</p> <p>8 what we call a drop line integration, right?</p> <p>9 So basically, then, the major</p> <p>10 one is still this monoester, which is a known</p> <p>11 degradant, but the other one become an</p> <p>12 unknown peak, right?</p> <p>13 So then my, you know, my group</p> <p>14 did a comprehensive, you know, investigation</p> <p>15 using LC-MS and also utilizing NMR, and so</p> <p>16 finally we were able to find, you know,</p> <p>17 another degradant that has been unknown for</p> <p>18 this particular, you know, you know, drug</p> <p>19 substances.</p> <p>20 And betamethasone dipropionate</p> <p>21 at the time, I think around maybe 2007 we did</p> <p>22 the investigation at, you know,</p> <p>23 Schering-Plough at the time, that product was</p> <p>24 already, I was told, on the market for like</p> | <p>1 Page 67</p> <p>1 degradation mechanism, you know, even for a</p> <p>2 product that has been on the market for</p> <p>3 nearly 30 years.</p> <p>4 There will still be, as I said,</p> <p>5 even with the progress, you know, of the</p> <p>6 technology, you know, better, you know,</p> <p>7 sensitivity, better, you know, specificity.</p> <p>8 You know, we're able to, you know, to find</p> <p>9 out, and also we're able to resolve those</p> <p>10 issues.</p> <p>11 So after that --</p> <p>12 Q. I'm sorry to interrupt. All I</p> <p>13 asked is if you recall any instances. I</p> <p>14 didn't ask you for the full story.</p> <p>15 A. Okay. All right. Okay, sorry.</p> <p>16 Yeah, I thought you...</p> <p>17 MR. GALLAGHER: Adam, we've</p> <p>18 been going about an hour and ten</p> <p>19 minutes. You can ask a few more</p> <p>20 questions, but maybe at some point we</p> <p>21 can take a break.</p> <p>22 MR. SLATER: Whatever you want</p> <p>23 to do.</p> <p>24 ///</p> |

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| <p>1 BY MR. SLATER:</p> <p>2 Q. I'm looking at your -- let's go</p> <p>3 to the first page, now, of the resume.</p> <p>4 A. Sure.</p> <p>5 So maybe after the resume</p> <p>6 question, we can take a break?</p> <p>7 MR. SLATER: Why don't you go</p> <p>8 take the break now.</p> <p>9 THE WITNESS: Okay. So we have</p> <p>10 what, 10, 15 minutes or what?</p> <p>11 MR. SLATER: Let's go off the</p> <p>12 record, please.</p> <p>13 THE VIDEOGRAPHER: The time</p> <p>14 right now is 8:12 a.m. We're now off</p> <p>15 the record.</p> <p>16 (Whereupon, a recess was</p> <p>17 taken.)</p> <p>18 THE VIDEOGRAPHER: The time</p> <p>19 right now is 8:27 a.m. We're back on</p> <p>20 the record.</p> <p>21 (Whereupon, Exhibit Number</p> <p>22 ZHP-293 was marked for</p> <p>23 identification.)</p> <p>24 BY MR. SLATER:</p> | <p>Page 70</p> <p>1 the most challenging, you know, issues, as I</p> <p>2 put there, yeah, the most challenging</p> <p>3 technical issues.</p> <p>4 Q. When I ask what CEMAT is, is it</p> <p>5 a laboratory or a separate office, or is</p> <p>6 it -- let me ask this question.</p> <p>7 In terms of what CEMAT is, is</p> <p>8 it part of ZHP?</p> <p>9 A. Yes.</p> <p>10 Q. Where is it located?</p> <p>11 A. It's located in headquarter of</p> <p>12 ZHP, E Linghai, Zhejiang Province, China.</p> <p>13 Q. Which facility?</p> <p>14 A. Which facility. It's in</p> <p>15 Xunqiao facility, yeah, Xunqiao site.</p> <p>16 Q. Why was it necessary for you to</p> <p>17 establish CEMAT?</p> <p>18 A. Why it's necessary?</p> <p>19 Q. Let me ask the question very</p> <p>20 specifically.</p> <p>21 What was the specific need --</p> <p>22 well, rephrase.</p> <p>23 What was the specific reason</p> <p>24 why CEMAT was established?</p> |
| <p>1 Q. On the screen is Exhibit 293.</p> <p>2 Do you recognize that document?</p> <p>3 A. Oh, yeah.</p> <p>4 Q. What is it?</p> <p>5 A. Right now it's just, you know,</p> <p>6 the starting of the summary of my LinkedIn</p> <p>7 page.</p> <p>8 MR. SLATER: All right.</p> <p>9 Cheryll, can you scroll down to where</p> <p>10 it talks about -- right there.</p> <p>11 Perfect. No. A little more up. Yes,</p> <p>12 perfect.</p> <p>13 Q. Your LinkedIn page says that</p> <p>14 you established something called CEMAT,</p> <p>15 C-E-M-A-T.</p> <p>16 A. Yes, CEMAT.</p> <p>17 Q. What is that?</p> <p>18 A. Basically, it's just like --</p> <p>19 you know, in the sense that I rebuilt my, you</p> <p>20 know, research team at Huahai.</p> <p>21 You know, the mission is pretty</p> <p>22 much the same, you know, you know, in terms</p> <p>23 of, you know, supporting those issues related</p> <p>24 to pharmaceutical impurities, and those are</p> | <p>Page 71</p> <p>1 A. Well, basically to improve, you</p> <p>2 know, the company's, you know, capability,</p> <p>3 you know, in this particular field.</p> <p>4 Q. And that field would include</p> <p>5 the identification of impurities in drug</p> <p>6 products?</p> <p>7 MR. GALLAGHER: Objection.</p> <p>8 Vague.</p> <p>9 THE WITNESS: I'm sorry.</p> <p>10 MR. GALLAGHER: You can answer.</p> <p>11 THE WITNESS: Okay.</p> <p>12 Yes, drug products as well as</p> <p>13 new drug substances.</p> <p>14 BY MR. SLATER:</p> <p>15 Q. Is API a drug substance?</p> <p>16 A. Yeah. API, yeah, is another</p> <p>17 name usually for drug substance, yes.</p> <p>18 Q. When I said "drug products,"</p> <p>19 you were thinking finished dose?</p> <p>20 A. Yes. That's usually people,</p> <p>21 you know, call it, yes.</p> <p>22 Q. The identification of</p> <p>23 impurities in drug substances is an important</p> <p>24 part of cGMP, correct?</p> |

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| <p>1 MR. GALLAGHER: Objection. 2 Vague. 3 You can answer. 4 THE WITNESS: Okay. 5 A. Identification is -- yes, it's 6 part of the cGMP requirements, yes. 7 MR. SLATER: Cheryll, let's put 8 up the next exhibit, this PowerPoint 9 that we have regarding CEMAT, just to 10 identify it for a moment. I believe 11 it's ZHP00404315 to 327. 12 (Whereupon, Exhibit Number 13 ZHP-294 was marked for 14 identification.) 15 A. The exhibit is gone? Okay. 16 BY MR. SLATER: 17 Q. Do you see the PowerPoint we've 18 put on the screen? 19 A. Yeah, sure. 20 Q. Did you create that PowerPoint? 21 A. My associates probably prepared 22 a draft and then I finalized it, yes. 23 Q. What was the purpose of 24 creating this PowerPoint?</p> | <p>Page 74</p> <p>1 Process impurities would 2 include, for example, the NDMA created 3 by the zinc chloride process; that's a 4 process impurity, correct? 5 A. Retrospectively, yes. 6 Q. And the creation of NDMA and 7 NDEA in the TEA process with sodium nitrite 8 quenching, those would be process impurities, 9 correct? 10 A. Right. 11 Q. And in both those -- rephrase. 12 After both those manufacturing 13 processes -- well, rephrase. 14 For the zinc chloride process, 15 the root cause of the creation of NDMA was 16 that the dimethylformamide was decomposing to 17 create dimethylamine, which then reacted 18 during the process with nitrous acid to 19 create NDMA, correct? 20 MR. GALLAGHER: Objection. 21 Vague, and foundation. 22 BY MR. SLATER: 23 Q. That's the root cause, correct? 24 A. Yeah, that's the root cause</p> |
| <p>1 A. Well, there's multiple 2 purposes. You know, one, just to present to, 3 you know, our colleagues, you know, and 4 sometimes, you know, present to, you know, to 5 my boss, you know, during the, like, 6 quarterly meetings, you know, particularly in 7 the early days. 8 You know, you need to, you 9 know, you need to show, you know, right, what 10 you can achieve.</p> <p>11 MR. SLATER: I'm sorry. Let's 12 go to the page after the cover page, 13 please? Perfect.</p> <p>14 Q. Looking at the Mission of 15 CEMAT, it says, "To solve the most 16 challenging technical problems encountered 17 from research and development to scale up and 18 manufacture of drug substances and finished 19 products, particularly those related to 20 process impurities, degradation products, and 21 solid state and polymorphism."</p> <p>22 Do you see that?</p> <p>23 A. Mm-hmm, sure.</p> <p>24 Q. When this -- rephrase.</p> | <p>Page 75</p> <p>1 A. Well, there's multiple 2 purposes. You know, one, just to present to, 3 you know, our colleagues, you know, and 4 sometimes, you know, present to, you know, to 5 my boss, you know, during the, like, 6 quarterly meetings, you know, particularly in 7 the early days. 8 You know, you need to, you 9 know, you need to show, you know, right, what 10 you can achieve.</p> <p>11 MR. SLATER: I'm sorry. Let's 12 go to the page after the cover page, 13 please? Perfect.</p> <p>14 Q. Looking at the Mission of 15 CEMAT, it says, "To solve the most 16 challenging technical problems encountered 17 from research and development to scale up and 18 manufacture of drug substances and finished 19 products, particularly those related to 20 process impurities, degradation products, and 21 solid state and polymorphism."</p> <p>22 Do you see that?</p> <p>23 A. Mm-hmm, sure.</p> <p>24 Q. When this -- rephrase.</p> |

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| <p>1 that I'm saying that is, you know, based upon 2 all of the new knowledge, right, that 3 accumulated by the industry, as well as, you 4 know, from the regulators, okay?</p> <p>5 For the formation for the TEA 6 process, for the formation of the TEA, 7 basically you have two mechanisms. One is 8 the DEA is a typical process impurity of TEA, 9 so DEA would also, yeah, would react with the 10 nitrous acid to perform NDEA.</p> <p>11 But also, according to, as I 12 said, again, updated, you know, you know, 13 information, the triethylamine could also 14 react with nitrous acid, but the efficiency 15 is not as high as the reaction with the TEA, 16 right?</p> <p>17 So -- yeah, so basically, you 18 know, that's the mechanism for that process, 19 okay, or the root cause.</p> <p>20 And for NDMA, for its presence 21 in the TEA process, and I think the root 22 cause is the -- in some of the TEA raw 23 material it may contain a trace amount of, 24 you know, of dimethylamine, okay, so that's</p> | <p>Page 78</p> <p>1 A. It was during, you know, again, 2 part of the retrospective, you know, 3 investigations.</p> <p>4 And also those knowledge, you 5 know, was not gained instantaneously. And 6 obviously, you know -- I mean, it's like if 7 you look at some of the FDA's -- their 8 training material, FDA's announcement, you 9 know, you know, this whole thing is very 10 complicated, you know, so it takes time and 11 great efforts, right?</p> <p>12 So you will first, you know, 13 reveal the most obvious, and then eventually, 14 you know, when time goes by, you know. And 15 so some of the other minor contributing 16 factors was also being, you know, discovered.</p> <p>17 Q. Before June of 2018, did ZHP 18 ever have any information indicating that any 19 of the valsartan manufacturing processes 20 could cause any nitrosamine to be created?</p> <p>21 A. No. The whole industry, as 22 well as the regulator, did not have that 23 knowledge, including ZHP.</p> <p>24 Q. And I've seen some vocabulary</p> |
| <p>1 one root cause.</p> <p>2 I think that there's another 3 root cause for the presence of NDMA in the 4 TEA process, which is from, you know, for -- 5 as far as I remember, for very limited, you 6 know, batch numbers. Because for some of 7 the, you know, product, they were 8 manufactured, you know, using the share line, 9 you know, with the zinc chloride valsartan. 10 And I think, you know, so for those limited 11 number of batches, that's another root cause.</p> <p>12 So I think that's pretty much, 13 you know, yeah, the root cause, you know, you 14 know, for the TEA process for NDMA and NDEA.</p> <p>15 Q. When you refer to the shared 16 production line, are you talking about 17 cross-contamination?</p> <p>18 A. Well, that's one way, you know, 19 from some of the inspections, you know, you 20 know, people use that phrase, but I would 21 say, rather, it's carryover, you know, of 22 some of the residual impurities.</p> <p>23 Q. And when was that learned?</p> <p>24 When was that root cause figured out?</p> | <p>Page 79</p> <p>1 in some things that I've read, so I just want 2 to make sure we're on the same page as to 3 what certain things mean as we go forward if 4 we could, please.</p> <p>5 A. No problem.</p> <p>6 Q. So I've seen the term 7 "nitrosamine" and I've seen the term "nitroso 8 compound" or "N-nitroso compound." 9 Does that all basically mean 10 the same thing?</p> <p>11 A. No. To be scientifically 12 precise, they are not the same.</p> <p>13 Nitroso compound is a very -- 14 you know, I'm a scientist, okay, right? If 15 somebody just tell me nitroso compound, you 16 know, you know, any compound have a nitroso 17 group, they're called a nitroso compound. So 18 nitrosamine is just a subtype of the nitroso 19 compound, all right?</p> <p>20 And the same thing, you know, 21 N-nitroso compound is also a subtype of 22 nitroso compound, but N-nitroso compound 23 including the nitrosamine.</p> <p>24 MR. SLATER: Cheryll, let's</p> |

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| <p>1 take this document down, and go to 2 document -- now what are we up to, 3 294? Is the next document 294? 4 Is the next exhibit 294? 5 THE STENOGRAPHER: 295. 6 MR. SLATER: 295. I'm always 7 off by one, Maureen. 8 (Whereupon, Exhibit Number 9 ZHP-295 was marked for 10 identification.) 11 MR. SLATER: Looking at Exhibit 12 295, let's put up ZHP00190573.</p> <p>13 BY MR. SLATER:</p> <p>14 Q. This is an e-mail dated 15 July 27, 2017.</p> <p>16 Do you see that?</p> <p>17 A. Okay.</p> <p>18 Q. Do you see the date in the top 19 right?</p> <p>20 A. Let's see. Yeah, uh-huh.</p> <p>21 Q. And you can see the person who 22 wrote it up in the top left. You can see 23 Jinsheng Lin.</p> <p>24 Do you see that?</p> | <p>Page 82</p> <p>1 MR. SLATER: The link, the 2 hopper. 3 (Whereupon, Exhibit Number 4 ZHP-296 was marked for 5 identification.) 6 A. That will be better for most of 7 you guys. Yeah, for me that's fine, but... 8 MR. SLATER: Okay if I proceed? 9 MR. GALLAGHER: Yes, please. I 10 see it. It's up.</p> <p>11 BY MR. SLATER:</p> <p>12 Q. So it says -- rephrase. 13 This e-mail dated by one of 14 your key technical people, Jinsheng Lin, it 15 says it's to multiple people. And I just -- 16 tell me if I get these names right. Jucai 17 Ge, Tianpei Huang, Wangwei Chen, Wenquan Zhu. 18 A. Okay. 19 Q. Wenbin Chen. 20 A. Uh-huh. 21 Q. Mr. Li. 22 A. That's me. Yeah, that's me. 23 Q. Peng Dong? 24 A. Wait a second. Oh, wait. I'm</p> |
| <p>1 A. Yes. He was, yeah, one of my 2 staff, yes.</p> <p>3 Q. What was his role? What was 4 his title?</p> <p>5 A. His title right now is 6 technical associate director, I think.</p> <p>7 Something like that, yeah.</p> <p>8 Q. Would it have been the same 9 title back in July of 2017?</p> <p>10 A. No. He had one -- at least one 11 promotion. He maybe at the time was like 12 assistant, you know, like technical director, 13 you know, but I don't, you know, keep those 14 things, you know, you know, you know, up and 15 running all the time in my mind. Yeah. But 16 he -- yeah, he is one of the key technical 17 person in my team.</p> <p>18 MR. GALLAGHER: Adam, do you 19 have an English language version of 20 this document?</p> <p>21 MR. SLATER: We do. I think 22 Cheryll can put it into that.</p> <p>23 MR. GALLAGHER: Into the link?</p> <p>24 Great.</p> | <p>Page 83</p> <p>1 still seeing the Chinese version. Are you 2 reading the English version?</p> <p>3 Q. I'm certainly not reading the 4 Chinese; I'm reading the English. But I'm 5 just going through the names right now.</p> <p>6 A. Yeah, sure. Yeah, go ahead.</p> <p>7 Q. So we just -- we established 8 you're one of the people who received this 9 e-mail, correct?</p> <p>10 A. Oh, yes.</p> <p>11 Q. Also Peng Dong?</p> <p>12 A. Mm-hmm.</p> <p>13 Q. Lihong Lin?</p> <p>14 A. Mm-hmm.</p> <p>15 Q. Yanfeng Liu?</p> <p>16 A. Yes, that's pretty close.</p> <p>17 Q. Peng Wang?</p> <p>18 A. Penh Wang, yes.</p> <p>19 Q. And Wenling Zhang.</p> <p>20 A. Yes.</p> <p>21 Q. Okay. And it looks like the 22 subject is "Valsartan Impurity K." 23 Does it say that, or is that an 24 attachment?</p> |

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| <p>1 A. Yeah, "Valsartan Impurity K," 2 yes. 3 Q. Okay. So the subject is 4 "Valsartan Impurity K," correct? 5 A. Yes, looks like, yes. 6 Q. And this is to -- it's 7 addressed to Ms. Ge. Is that pronounced 8 right, G-E, Ge? 9 A. Yeah, yeah. Yes. That's 10 perfect almost, yes. 11 Q. And they're talking about 12 impurity they see in one of the production 13 processes, correct? 14 A. Yeah, mm-hmm. 15 MR. SLATER: And let's turn to 16 the second page now of the document, 17 please, at the top. 18 Q. Tell me if I have this pretty 19 much correct. At the top it says, "Through 20 the secondary mass spectrometry analysis" -- 21 and I want to stop there. 22 What is secondary mass 23 spectrometry analysis? 24 A. It's basically you have --</p> | <p>Page 86</p> <p>1 N-nitrosodimethylamine that occurs in 2 valsartan when quenched with sodium nitrite, 3 and its structure is very toxic. Its 4 possible formation route is shown as 5 follows," and then we have the diagrams. 6 Did I get that right? 7 A. Yeah, yeah, it looks like. 8 Q. And if we go further down below 9 the pictures, there is the second paragraph 10 after the pictures. 11 MR. SLATER: You can keep 12 scrolling down, please, Cherryl. 13 Q. Looking now at the second 14 paragraph under the diagrams, the e-mail 15 says, "If it is confirmed as the above 16 speculated structure, then its toxicity will 17 be very strong, and there will be an 18 extremely high GMP risk. This is a common 19 problem in the production and synthesis of 20 sartan APIs. It is recommended to improve 21 other quenching processes (such as NaClO) 22 along with the optimization of the valsartan 23 sodium azide quenching process." 24 Did I get that pretty much</p> |
| <p>1 well, actually, you know, you have three 2 stages. You're going to the -- first the 3 mass detector, right? It's looking for the 4 parent molecule away, or the parent most 5 usually like protonated molecular eye. 6 And then you're going to a 7 collision cell, you know, you know, you know, 8 usually with gas, either nitrogen, helium, 9 or, you know, some other gas, and to break 10 them apart. 11 And then you have, you know, a 12 number of, you know, you know, what do we 13 call it, fragments, right? And then you go 14 to another, you know, mass detector. Yeah. 15 So sometimes it's also called a triple quad 16 mass spectrometry, but sometimes just called 17 MS2 or /MS. 18 Q. Again starting -- rephrase. 19 Starting at the top, it says, 20 "Through the secondary mass spectrometry 21 analysis, it can be inferred that the extra 22 NO substituent is in the cyclic compound 23 fragment, and it is very likely that it is an 24 N-NO compound; it is similar to the</p> | <p>Page 87</p> <p>1 right? 2 A. Yeah, it sounds like. Yeah. 3 Q. And then going to the last 4 paragraph of this e-mail you received 5 July 27, 2017, it says, "I've also attached a 6 patent of a 2013 sodium azide NaClO quenching 7 method by Zhejiang Second Pharma Co., 8 Limited. They proposed that the use of NaNO2 9 quenching will result in the formation of 10 N-NO impurities. At the same time, they used 11 ZHP's crude Valsartan in their LC-MS test and 12 detected this impurity. This indicates that 13 other companies have paid attention to the 14 quality problem very early on. So leaders 15 please pay attention to this issue." 16 And then it's signed Jinsheng 17 Lin, CEMAT, July 27, 2017, correct? 18 A. Yeah, looks like, uh-huh. 19 Q. And if we go back up to the top 20 now, just to reiterate a couple things, it 21 said in part that what was being seen here 22 was similar to the NDMA that occurs in 23 valsartan when quenched with sodium nitrite, 24 correct? You saw that language up at the</p> |

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| <p>1 top?</p> <p>2 A. Yes.</p> <p>3 MR. GALLAGHER: Objection.</p> <p>4 Vague, and mischaracterizes the</p> <p>5 document.</p> <p>6 BY MR. SLATER:</p> <p>7 Q. And, therefore, as of July 27,</p> <p>8 2017, you and others in your company knew</p> <p>9 that when valsartan was quenched with sodium</p> <p>10 nitrite, it was forming in NDMA, correct?</p> <p>11 MR. GALLAGHER: Objection.</p> <p>12 Again, vague and mischaracterizes the</p> <p>13 document.</p> <p>14 A. You know, you know, I have</p> <p>15 received a lot of e-mails, and it looks like</p> <p>16 my name was there. But somehow I don't know,</p> <p>17 you know -- you know, he didn't specifically</p> <p>18 follow up with me or brought that, you know,</p> <p>19 specifically to my attention.</p> <p>20 BY MR. SLATER:</p> <p>21 Q. Well, that's what the e-mail</p> <p>22 says, right?</p> <p>23 A. Right, right, I know. Yeah, I</p> <p>24 know that my name was there, but I, you know,</p> | <p>Page 90</p> <p>1 You can answer, Dr. Li.</p> <p>2 A. I'm sorry, what is the question</p> <p>3 again? Sorry.</p> <p>4 BY MR. SLATER:</p> <p>5 Q. Sure.</p> <p>6 When people outside ZHP learned</p> <p>7 that the valsartan manufacturing process was</p> <p>8 creating NDMA, that was a significant GMP</p> <p>9 problem, correct?</p> <p>10 A. Well, that's what he said, yes.</p> <p>11 Q. And he also said this is a</p> <p>12 common problem in the production and</p> <p>13 synthesis of sartan APIs. So at that point</p> <p>14 people within ZHP knew that with the</p> <p>15 manufacture of their sartan APIs,</p> <p>16 nitrosamines were being created.</p> <p>17 That's what he's referring to</p> <p>18 in this e-mail, correct?</p> <p>19 A. That, it looks like, is the</p> <p>20 case.</p> <p>21 Q. And then he says, "It is</p> <p>22 recommended to improve other quenching</p> <p>23 processes (such as NaClO)."</p> <p>24 And if you could translate that</p> |
| <p>1 receive huge amount of e-mail.</p> <p>2 Usually, you know, for</p> <p>3 something -- I told them if something, you</p> <p>4 know, you know, they feel important, they</p> <p>5 should remind me or, you know, you know,</p> <p>6 brought up, you know, to my attention.</p> <p>7 Q. And going down further to that</p> <p>8 second-to-last paragraph we read, just to</p> <p>9 reiterate and walk through, Jinsheng Lin had</p> <p>10 written, "If it is confirmed as the above</p> <p>11 speculated structure, then its toxicity will</p> <p>12 be very strong, and there will be an</p> <p>13 extremely high GMP risk."</p> <p>14 That's what he wrote, correct?</p> <p>15 A. That's what he wrote, but, you</p> <p>16 know, he's not a toxicologist, so I think</p> <p>17 that's his speculation.</p> <p>18 Q. Well, certainly with regard to</p> <p>19 NDMA in valsartan, that would be, and turned</p> <p>20 out to be, a significant GMP problem when it</p> <p>21 was discovered outside of ZHP, correct?</p> <p>22 A. Let me see. Which --</p> <p>23 MR. GALLAGHER: Objection.</p> <p>24 Calls for speculation.</p> | <p>Page 91</p> <p>1 for me, please.</p> <p>2 A. I'm sorry, which one here?</p> <p>3 Q. The NaClO. Is that sodium</p> <p>4 nitrite?</p> <p>5 A. No. That's the -- no, that's</p> <p>6 another quenching reagent. No, it's not</p> <p>7 sodium nitrite.</p> <p>8 Q. What is it?</p> <p>9 A. It's one of the</p> <p>10 chloro-containing, you know, acid. This one</p> <p>11 is actually the main ingredient in bleach.</p> <p>12 Q. Hypochlorite.</p> <p>13 A. Yeah.</p> <p>14 Q. Is that hypochlorite?</p> <p>15 A. Yeah, I think it should be that</p> <p>16 one, yes.</p> <p>17 Q. Let me ask it again then, now</p> <p>18 that I just figured it out with you.</p> <p>19 With my -- all right. Let me</p> <p>20 rephrase.</p> <p>21 He wrote, "It is recommended to</p> <p>22 improve other quenching processes, such as</p> <p>23 hypochlorite" -- that's actually bleach,</p> <p>24 right?</p> |

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| <p>1 A. Yes.</p> <p>2 Q. -- "along with the optimization 3 of the valsartan sodium azide quenching 4 process."</p> <p>5 So he's recommending that the 6 sodium azide quenching process that you had 7 been using be optimized, be improved, 8 correct?</p> <p>9 A. Looks like, yes.</p> <p>10 Q. And going back to the next 11 paragraph, he actually points out that he is 12 attaching a patent, which we'll pull out in 13 just a moment, from a 2013 sodium azide 14 hypochlorite quenching method by a different 15 company, Zhejiang Second Pharma Co., Limited.</p> <p>16 That's another company in 17 China, correct?</p> <p>18 A. Yes.</p> <p>19 Q. And, again, the NaClO, that's 20 hypochlorite, which is bleach, correct?</p> <p>21 A. Yes.</p> <p>22 Q. And he says that that company 23 "proposed that the use of NaNO₂ quenching 24 will result in the formation of N-NO</p> | <p>Page 94</p> <p>1 A. Yeah, mm-hmm.</p> <p>2 Q. And again, as I'm going to show 3 you in a moment, he's talking about what he 4 read in this patent by this other company in 5 China.</p> <p>6 And he then says, "This 7 indicates that other companies have paid 8 attention to the quality problem very early 9 on."</p> <p>10 Do you see that?</p> <p>11 A. Mm-hmm.</p> <p>12 Q. And this quality problem he's 13 talking about is the sodium nitrite quenching 14 leading to the creation of nitrosamines, 15 correct?</p> <p>16 A. Looks like.</p> <p>17 Q. And he then says, "So leaders 18 please pay attention to this issue."</p> <p>19 And when he's referring to 20 "leaders," would that be the people on this 21 e-mail, including yourself and Peng Dong and 22 Lihong Lin, and the others on that e-mail?</p> <p>23 MR. GALLAGHER: Objection.</p> <p>24 Vague, and calls for speculation.</p> |
| <p>1 impurities."</p> <p>2 NaNO₂ is sodium nitrite, 3 correct?</p> <p>4 A. NaNO₂, yes.</p> <p>5 Q. And N-NO impurities would be 6 nitrosamine impurities, correct?</p> <p>7 A. I'm sorry, which one?</p> <p>8 Q. Where it says "N-NO," those 9 would be nitrosamine impurities, correct?</p> <p>10 A. I'm sorry. I don't know which 11 you're referring to.</p> <p>12 MR. SLATER: Scroll down a 13 little, Cherryl. I think it's cut 14 off.</p> <p>15 Q. In the last paragraph?</p> <p>16 A. Oh, yeah. Yeah, it's N-NO, 17 yeah, impurity, yes. It's N-nitro impurity, 18 yes.</p> <p>19 Q. And he then says, "At the same 20 time, they used ZHP's crude Valsartan in 21 their LC-MS test and detected this impurity."</p> <p>22 And "LC-MS," that would be 23 liquid chromatography-mass spectrometry? Do 24 I have that right?</p> | <p>Page 95</p> <p>1 You can answer, Dr. Li.</p> <p>2 A. Yeah, it looks like at least 3 the two, yes.</p> <p>4 BY MR. SLATER:</p> <p>5 Q. Now let's go, if we could -- 6 well, actually, let me ask you this question.</p> <p>7 This e-mail -- we have 8 something called metadata, and metadata is 9 information we get when we get produced 10 documents; where they came from, who authored 11 them, etcetera. That's something we exchange 12 as part of this litigation.</p> <p>13 A. Okay.</p> <p>14 Q. The metadata on this said that 15 this came from a folder titled "Documents" 16 from your old computer, which apparently, 17 according to the metadata, was copied from 18 your old desktop into your new computer in or 19 about June 2018.</p> <p>20 Do you remember doing that?</p> <p>21 A. I'm sorry?</p> <p>22 MR. GALLAGHER: Objection.</p> <p>23 Objection. Vague and foundation.</p> <p>24 ///</p> |

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| <p>Page 98</p> <p>1 BY MR. SLATER:</p> <p>2 Q. Do you remember doing that,</p> <p>3 copying this document from one computer into</p> <p>4 another computer in or about June of 2018?</p> <p>5 A. I didn't do that.</p> <p>6 Q. So if that happened, somebody</p> <p>7 else would have done it, and that would have</p> <p>8 been stored in --</p> <p>9 A. Probably IT, yeah. As I</p> <p>10 said -- yeah.</p> <p>11 Q. So this e-mail clearly is --</p> <p>12 rephrase.</p> <p>13 So based on this e-mail, your</p> <p>14 company was -- well, let me rephrase this.</p> <p>15 Did your company ever tell the</p> <p>16 FDA or any other regulators about its</p> <p>17 knowledge about the creation of nitrosamines</p> <p>18 including NDMA from the quenching with sodium</p> <p>19 nitrite?</p> <p>20 Do you recall your company</p> <p>21 telling the FDA or any regulatory authorities</p> <p>22 about that?</p> <p>23 A. Well --</p> <p>24 MR. GALLAGHER: Objection.</p> | <p>Page 100</p> <p>1 compound with irbesartan, yeah. It's not</p> <p>2 valsartan. But based upon that, yeah, it</p> <p>3 looks like he's making -- you know, making</p> <p>4 his guess.</p> <p>5 Q. Well, he's comparing it and</p> <p>6 calling it similar to the NDMA that forms in</p> <p>7 valsartan when quenched with sodium nitrite.</p> <p>8 That's what he said, right?</p> <p>9 A. Yeah, that's -- again, you</p> <p>10 know, you know, that's his, you know, his</p> <p>11 guess or his speculation.</p> <p>12 Q. Well, he doesn't say he's</p> <p>13 guessing or speculating, does he?</p> <p>14 A. He didn't say, but basically</p> <p>15 from the context, you know, yeah. I mean,</p> <p>16 it's obvious.</p> <p>17 Q. Well, it's also obvious he said</p> <p>18 in the second-to-last paragraph, if we scroll</p> <p>19 down to it, that "If it is confirmed as the</p> <p>20 above speculated structure in this</p> <p>21 irbesartan, then its toxicity will be very</p> <p>22 strong, and there will be an extremely high</p> <p>23 GMP risk."</p> <p>24 Meaning if it's a nitrosamine,</p> |
| <p>Page 99</p> <p>1 Vague.</p> <p>2 A. In this particular case, you</p> <p>3 know, he's talking -- well, that particular</p> <p>4 case with, you know, irbesartan, right? And</p> <p>5 so he's, you know, you know, you know, making</p> <p>6 a kind of a, you know, you know, guess.</p> <p>7 You know, I mean, all of the</p> <p>8 language that you can see, you know, you</p> <p>9 know, yeah, because the reaction, you know,</p> <p>10 that he showed is irbesartans, yeah.</p> <p>11 BY MR. SLATER:</p> <p>12 Q. Well, if we go to the top of</p> <p>13 this page --</p> <p>14 MR. SLATER: Could you scroll</p> <p>15 up, please, Cheryll, the top of the</p> <p>16 second page? Thanks.</p> <p>17 Q. -- just to be clear, he</p> <p>18 specifically said that "It is similar to the</p> <p>19 NDMA that occurs in valsartan when quenched</p> <p>20 with sodium nitrite," and it's very toxic.</p> <p>21 A. That's -- he's, you know, you</p> <p>22 know -- yeah, he's making a guess. Yeah,</p> <p>23 because -- because, you know, what he found</p> <p>24 is, you know, is this N-, you know, nitroso</p> | <p>Page 101</p> <p>1 it's going to be very toxic, and that's going</p> <p>2 to be a significant GMP problem, right?</p> <p>3 That's what he said in this</p> <p>4 e-mail, correct?</p> <p>5 A. He said that; but, again, you</p> <p>6 know, he's not a toxicologist, right? And</p> <p>7 now we know, you know, based upon, you know,</p> <p>8 some of the FDA's training -- you know,</p> <p>9 training material, not all, you know,</p> <p>10 N-nitroso compound are, you know, as toxic,</p> <p>11 okay.</p> <p>12 Quite a few of them, if you</p> <p>13 look at FDA's training, you know, PPTs there</p> <p>14 are quite of few N-nitroso compound that they</p> <p>15 are not, you know, not, you know, you know,</p> <p>16 you know, genotoxic, or they are not</p> <p>17 mutagenic.</p> <p>18 So, again, you know, yeah, he's</p> <p>19 making, you know, you know, his own judgment,</p> <p>20 you know, outside of his, you know, you know,</p> <p>21 you know, expertise.</p> <p>22 Q. He turned out to be correct,</p> <p>23 right? Because NDMA and NDEA are considered</p> <p>24 to be mutagenic/genotoxic impurities,</p> |

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| <p>1 correct?</p> <p>2 MR. GALLAGHER: Objection.</p> <p>3 Calls for speculation.</p> <p>4 You can answer.</p> <p>5 A. Yeah. Right now, yeah. And</p> <p>6 it's considered as probable, you know, you</p> <p>7 know, carcinogenic, you know, to human. But</p> <p>8 it's, you know, it's probable.</p> <p>9 And also, again, based upon,</p> <p>10 you know, some recent FDA's training</p> <p>11 material, you know, I just went through as</p> <p>12 part of the preparation.</p> <p>13 And endogenously formed NDMA</p> <p>14 could be, you know, somewhere between 1,000</p> <p>15 or even greater than 2,000 microgram per day.</p> <p>16 You know, basically, you know, those NDMA,</p> <p>17 they -- you know, you know, you know, it is</p> <p>18 formed, you know, inside the body, like</p> <p>19 inside a human body, after, you know,</p> <p>20 ingestion, you know, of regular foods.</p> <p>21 Q. NDMA was being formed by the</p> <p>22 manufacturing process, as we agreed earlier.</p> <p>23 It was a process impurity in the valsartan,</p> <p>24 correct?</p> | <p>Page 102</p> <p>1 know, as I indicated for the TEA process, you</p> <p>2 know, based upon my knowledge</p> <p>3 retrospectively, only very limited batch, you</p> <p>4 know, had NDMA exceeding, you know, the</p> <p>5 limit, as well as for -- I think for the --</p> <p>6 for NDEA, there's also limited numbers.</p> <p>7 So for the TEA process, as far</p> <p>8 as I can remember, the vast majority of the</p> <p>9 batches, they still met the acceptable -- the</p> <p>10 current acceptable limit, although those</p> <p>11 limits are retrospective.</p> <p>12 BY MR. SLATER:</p> <p>13 Q. The zinc chloride process,</p> <p>14 every single batch that was manufactured and</p> <p>15 then sold in the United States exceeded the</p> <p>16 limit set by the FDA, correct?</p> <p>17 MR. GALLAGHER: Objection.</p> <p>18 Outside the scope.</p> <p>19 You can answer.</p> <p>20 A. Okay, retrospectively, yes.</p> <p>21 But, you know, to be clear, you know, there</p> <p>22 was no specification before the events.</p> <p>23 BY MR. SLATER:</p> <p>24 Q. When Jinsheng Lin said at the</p> |
| <p>Page 103</p> <p>1 A. Yes.</p> <p>2 Q. And it would never be</p> <p>3 acceptable to have NDMA at the levels it was</p> <p>4 found in your company's valsartan. That</p> <p>5 would never be acceptable, that could never,</p> <p>6 ever be permissible, correct?</p> <p>7 MR. GALLAGHER: Objection.</p> <p>8 Lacks foundation, and outside the</p> <p>9 scope.</p> <p>10 A. Yeah, that's not accurate,</p> <p>11 okay? That's not accurate. If you look at</p> <p>12 FDA's -- you know, at least the most recent,</p> <p>13 you know, there is an acceptable limit for</p> <p>14 NDMA or NDEA, okay?</p> <p>15 BY MR. SLATER:</p> <p>16 Q. Are you aware that every single</p> <p>17 batch of valsartan manufactured with both the</p> <p>18 sodium nitrite quenching process with TEA and</p> <p>19 the zinc chloride process, that every single</p> <p>20 batch exceeded the FDA's stated limits?</p> <p>21 Are you aware of that?</p> <p>22 MR. GALLAGHER: Objection.</p> <p>23 Outside the scope.</p> <p>24 A. That's not accurate, okay? You</p> | <p>Page 105</p> <p>1 end of this e-mail, "This indicates that</p> <p>2 other companies have paid attention to the</p> <p>3 quality problem very early on," when he was</p> <p>4 referring to the 2013 patent application, and</p> <p>5 then said, "So leaders please pay attention</p> <p>6 to this issue," he was giving you a good</p> <p>7 warning that this needed to be taken care of</p> <p>8 and fixed right away, because it was a</p> <p>9 serious quality problem with a very toxic</p> <p>10 substance, correct?</p> <p>11 MR. GALLAGHER: Objection.</p> <p>12 Vague, and mischaracterizes the</p> <p>13 document.</p> <p>14 A. As I said, you know, you know,</p> <p>15 now looking back, you know, you know, he's</p> <p>16 making, you know, his judgment, okay.</p> <p>17 Also, he's -- you know,</p> <p>18 particularly with regard to the potential</p> <p>19 toxicity of NDMA, because he's not a</p> <p>20 toxicologist.</p> <p>21 BY MR. SLATER:</p> <p>22 Q. Well, he was right that this</p> <p>23 was a quality problem and that it needed to</p> <p>24 be taken care of. That was a good decision</p> |

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| <p>1 by him to recommend to you and the other 2 leaders to fix this problem, this quality 3 problem, in 2017, right?</p> <p>4 MR. GALLAGHER: Objection. 5 Vague, and calls for speculation. 6 A. Again, as I said, you know, 7 he's making, you know, you know, those 8 guesses.</p> <p>9 BY MR. SLATER: 10 Q. Whatever you want to call it, 11 he was correct, right? 12 A. Again, you know, he's making 13 those speculations outside of his, you know, 14 expertise.</p> <p>15 Q. Let's go to -- well, rephrase. 16 Let me just tie this up.</p> <p>17 When people outside ZHP found 18 out what ZHP knew at least as of July 2017, 19 and likely earlier, since he's talking about 20 what was already known, when the rest of the 21 world found out about it, you couldn't sell 22 your valsartan anymore because of the 23 contamination with the NDMA, correct?</p> <p>24 MR. GALLAGHER: Objection.</p> | <p>Page 106</p> <p>1 So I can represent to you that 2 on the metadata, this is the attachment 3 referred to as the patent application. Do 4 you see that? With an application 5 announcement date of March 5, 2014 in the top 6 right.</p> <p>7 A. Yes.</p> <p>8 MR. SLATER: And just for the 9 record, Cheryll, could you scroll to 10 the bottom, and we'll just read off 11 the Bates number that is printed on 12 this?</p> <p>13 It says ZHP01812101.</p> <p>14 Now, if you could scroll down a 15 little more, Cheryll. Let's just get 16 the abstract fully shown here. No, 17 no, the other way. The other up. 18 Perfect.</p> <p>19 Q. Looking at the Abstract of this 20 patent application, I want to go down to the 21 last long sentence at the bottom, and it says 22 starting six lines from the bottom, "In the 23 method of the present invention, the use of 24 hypochlorite can cut off the source of</p> |
| <p>1 Vague, and outside the scope. 2 A. Again, you know, as I said, 3 he's making his speculations.</p> <p>4 BY MR. SLATER: 5 Q. Well, whatever you want to call 6 it, he was correct that the sodium nitrite 7 quenching was creating nitrosamines, which 8 was a serious GMP problem, correct? 9 MR. GALLAGHER: Objection. 10 Vague, and outside the scope. 11 You can answer. 12 A. In terms of a GMP, you know, 13 Ms. Ge would be in a better position, you 14 know, to answer that. 15 MR. SLATER: Let's go, Cheryll, 16 if we could, to the patent application 17 referred to here. Let's go to the 18 English version. 19 (Whereupon, Exhibit Numbers 20 ZHP-297 and ZHP-298 were marked for 21 identification.) 22 BY MR. SLATER: 23 Q. We're just getting the document 24 up. Great.</p> | <p>Page 107</p> <p>1 nitrous acid and eliminate the generation of 2 valsartan impurity K, and, with the 3 adjustment of other conditions, it can 4 prevent the generation of other impurities 5 that are difficult to handle, allowing the 6 preparation of high-purity valsartan 7 products."</p> <p>8 Do you see that?</p> <p>9 A. Mm-hmm.</p> <p>10 Q. And per the e-mail that we just 11 went through from Mr. Lin, he talked about 12 how the people who filed this patent at this 13 other company actually were looking at a way 14 to prevent these nitrosamine impurities from 15 forming by substituting something else for 16 sodium nitrite.</p> <p>17 Do you recall we just went 18 through that?</p> <p>19 A. Yes. But here, you know, you 20 know, based upon what I see here, right, this 21 patent is specifically, you know, talking 22 about, you know, the impurity K, okay?</p> <p>23 So retrospectively we know 24 that, you know, the impurity K is an</p> |

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| <p style="text-align: right;">Page 110</p> <p>1 N-nitroso impurity, right, but that impurity, 2 it looks like, you know, you know, Novartis, 3 they already knew, right, during their 4 initial filing. Okay. And also they did an 5 Ames test of the so-called impurity K, and it 6 turns out, you know, the Ames test results 7 was negative, right?</p> <p>8 So according to a European, you 9 know, authority document, this impurity, you 10 know, you know, has been controlled as a 11 regular normal impurity, okay, at the level 12 of 1,000 ppm.</p> <p>13 Q. I guess we could talk about 14 that for a moment.</p> <p>15 You realize that whatever the 16 results of the Ames test was, the regulatory 17 authorities said it should be treated as a 18 mutagenic genotoxic impurity, correct?</p> <p>19 MR. GALLAGHER: Objection. Foundation, calls for speculation, and outside the scope.</p> <p>22 You can answer.</p> <p>23 A. According to M7, if the results 24 of Ames test, if it's negative, you could</p> | <p style="text-align: right;">Page 112</p> <p>1 BY MR. SLATER:</p> <p>2 Q. NDMA and NDEA are not treated 3 as regular impurities; they're treated as 4 what they are, potent genotoxic impurities, 5 correct?</p> <p>6 MR. GALLAGHER: Objection. Vague, and calls for speculation.</p> <p>8 A. They are different. NDMA, you 9 know, you know, you know, every N-nitroso 10 compound, they are different. As I, you 11 know, early -- you know, you know, early on, 12 as I indicated, there are quite a few, you 13 know, N-nitroso, you know, compounds, they 14 are not mutagenic.</p> <p>15 MR. SLATER: Hang on. Let's 16 see where I want to go to now in this 17 document.</p> <p>18 Let's go to page 5, 19 paragraph 17, please. No, we're way 20 past it. Paragraph 17. I see what 21 you're doing, actually. You're right. 22 There you go. Perfect.</p> <p>23 Q. Paragraph -- or Section -- 24 rephrase.</p> |
| <p style="text-align: right;">Page 111</p> <p>1 control that or treat that as a regular 2 impurity.</p> <p>3 So in this particular case, 4 impurity K has been treated by Novartis, 5 which is the original innovator of valsartan 6 as a regular impurity. So its level is at 7 1,000 ppm.</p> <p>8 BY MR. SLATER:</p> <p>9 Q. Let's look at -- well, 10 rephrase.</p> <p>11 You're aware that the 12 regulatory authorities actually determined 13 not to treat it as a regular impurity and 14 said it had to be treated as a genotoxic 15 impurity, correct?</p> <p>16 MR. GALLAGHER: Objection.</p> <p>17 A. Not for -- sorry.</p> <p>18 MR. GALLAGHER: Go ahead.</p> <p>19 Outside the scope.</p> <p>20 You can answer.</p> <p>21 A. Yeah, not for impurity K. As I 22 said, impurity K has been controlled as a 23 regular impurity, although it is N-nitroso 24 impurities.</p> | <p style="text-align: right;">Page 113</p> <p>1 Section 17 is talking about -- 2 well, actually, let's go -- yeah, all right. 3 Rephrase.</p> <p>4 In 17 it talks about, "In the 5 present invention, the improvement of Step 3 6 reaction can effectively prevent valsartan 7 impurity K from forming; since valsartan 8 impurity K is a nitroso compound that is 9 highly toxic, the control of impurity K in 10 valsartan so that it is not detected is the 11 objective of the valsartan preparation method 12 of the present invention."</p> <p>13 Do you see what I just read?</p> <p>14 A. Yes.</p> <p>15 MR. SLATER: Now let's go, if 16 we could, to paragraph number 33.</p> <p>17 Q. It says in paragraph 33, 18 starting in the second sentence, "Through the 19 control of the reaction conditions, the 20 valsartan product is synthesized while the 21 formation of other impurities is minimized, 22 allowing effective control of the content of 23 impurities, thereby preparing high-purity 24 valsartan products, and enhancing their</p> |

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| <p style="text-align: right;">Page 114</p> <p>1 quality, which is of great significance for 2 ensuring the safety of valsartan APIs."</p> <p>3 Do you see that?</p> <p>4 A. Mm-hmm.</p> <p>5 Q. And you would certainly agree 6 with me that if you could prevent the 7 creation of nitrosamines by substituting 8 something for sodium nitrite, that's good for 9 safety, correct?</p> <p>10 A. This is something unknown, and 11 it's speculative. Because if you use other 12 quenching, you know, reagent, you might 13 create something new, some -- you know, some 14 new problems, okay.</p> <p>15 Q. That's why you test it and 16 study it before you sell it on the market for 17 patients to take it, right?</p> <p>18 MR. GALLAGHER: Objection. 19 Vague.</p> <p>20 A. Yes. You will do the -- yeah, 21 you will do the risk analysis. But based 22 upon the claim, you know, you know, in this 23 patent, you know, particularly with regard to 24 impurity K, you know, they claim is highly</p> | <p style="text-align: right;">Page 116</p> <p>1 yeah. Well, he sent it to other people. 2 Yeah.</p> <p>3 Q. And this would have been 4 available to and would have been reviewed by 5 your company most likely in 2014 when it was 6 available to be seen, correct?</p> <p>7 A. I don't know.</p> <p>8 MR. GALLAGHER: Objection. 9 Calls for speculation.</p> <p>10 MR. SLATER: All right. Let's 11 go to the next document. We can take 12 this down. Cheryll, let's go to 13 ZHP02336567.</p> <p>14 (Whereupon, Exhibit Number 15 ZHP-299 were marked for 16 identification.)</p> <p>17 BY MR. SLATER:</p> <p>18 Q. Do you see that on the screen? 19 A. Mm-hmm.</p> <p>20 Q. Okay. You see the title is 21 "Valsartan Patent Investigation Report"? Is 22 that a fair reading of that?</p> <p>23 A. Yeah, it's accurate.</p> <p>24 Q. And if you turn now to the next</p> |
| <p style="text-align: right;">Page 115</p> <p>1 toxic, but actually it is not based upon, you 2 know, the knowledge that we know today.</p> <p>3 BY MR. SLATER:</p> <p>4 Q. Well, you're not saying NDMA 5 and NDEA aren't toxic, because they're 6 accepted to be highly toxic and unacceptable 7 to be included in the API.</p> <p>8 A. Well, I am -- the focus of this 9 patent is, you know, is impurity K, okay. So 10 anything, you know, you know, beyond that, 11 you know, is their speculation, right?</p> <p>12 And also, you know, they claim 13 vitamin -- I'm sorry -- the impurity K, you 14 know, is highly toxic, you know, based upon, 15 you know, whatever, you know, available from 16 either European regulatory, you know, you 17 know, agency, I think this statement is not 18 correct.</p> <p>19 Q. We've confirmed as through the 20 e-mail we went through from Mr. Lin earlier 21 that your company had this patent in its 22 files, correct?</p> <p>23 A. You know, right. It looks like 24 at least Mr. Lin has it. I don't know --</p> | <p style="text-align: right;">Page 117</p> <p>1 page -- and we didn't bring up the whole 2 document for time's sake, but let's go to the 3 second page of this document, which is page 4 ZHP02336682.</p> <p>5 You can see in the middle of 6 the page the patent number of CN 103613558, 7 which is the patent number that was on the 8 patent we just looked at.</p> <p>9 Do you see that?</p> <p>10 A. Mm-hmm.</p> <p>11 MR. GALLAGHER: I'm going to 12 object to the extent this document -- 13 it appears you're representing that 14 this document is incomplete, so I'm 15 just going to object to that extent.</p> <p>16 But you can proceed with your 17 questions.</p> <p>18 MR. SLATER: What I'm 19 representing is that we have the front 20 for you, and we have this page, 21 because that's what we wanted to talk 22 about. But we certainly can provide 23 you the entire document if you want at 24 the break, if you want to go through</p> |

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| <p style="text-align: right;">Page 118</p> <p>1 it. We were just wanting to focus on 2 this for time purposes.</p> <p>3 MR. GALLAGHER: I'm just making 4 clear for the record, you know, if 5 your questions -- you're happy with an 6 incomplete document.</p> <p>7 MR. SLATER: Are you objecting 8 to my use of the document in this 9 form?</p> <p>10 MR. GALLAGHER: I'm just noting 11 an objection that the document is 12 incomplete. I don't know what is in 13 the rest of the document. If for your 14 questions you feel like the cover page 15 and this page is insufficient --</p> <p>16 BY MR. SLATER:</p> <p>17 Q. Okay. So looking now at the 18 section we're talking about now, it says the 19 title of the invention was "A Method for 20 Preparing Valsartan," correct?</p> <p>21 A. Yes.</p> <p>22 Q. The applicant was Zhejiang 23 Second Pharma Company, Limited, correct?</p> <p>24 A. Yes.</p> | <p style="text-align: right;">Page 120</p> <p>1 looks like, you know, based upon the material 2 that you just showed, you know, it just 3 didn't specifically mention, you know, 4 anything else. You know, it just vaguely 5 say, you know, for all other or other 6 impurities, but it just -- there is no 7 specification, you know, specifics.</p> <p>8 BY MR. SLATER:</p> <p>9 Q. I'm just honestly trying to 10 just establish the time period when it was 11 reviewed.</p> <p>12 A. Yeah, that's fine. Yeah, yeah, 13 that's fine, yeah.</p> <p>14 Q. Okay. So you could agree based 15 on what I've told you this was reviewed 16 likely in 2014 by someone in your company, 17 correct?</p> <p>18 MR. GALLAGHER: Objection. 19 Foundation, and calls for speculation.</p> <p>20 A. It looks like it.</p> <p>21 MR. SLATER: I think we have -- 22 Cherryl, do you have the second 23 document also where this is referred 24 to, the second ZHP document?</p> |
| <p style="text-align: right;">Page 119</p> <p>1 Q. And if you go down to the 2 bottom so that we can cut to the chase, it 3 says, "Patent infringement analysis. The 4 Huahai process does not add sodium 5 hypochlorite, so it does not constitute an 6 infringement."</p> <p>7 Do you see that?</p> <p>8 A. Mm-hmm.</p> <p>9 Q. And I can tell you from the 10 metadata this document was last modified 11 November 4, 2014, according to the document.</p> <p>12 If that's what the metadata 13 shows, you would expect that your company had 14 access to and reviewed that patent in 2014, 15 correct?</p> <p>16 MR. GALLAGHER: Objection. 17 Foundation, and compound.</p> <p>18 A. It looks like this -- you know, 19 you know, we have a patent group, okay, and 20 it looks like this is a report generated, you 21 know, by that patent, you know, group, okay.</p> <p>22 And again, you know, this 23 particular patent, the focus is related to 24 impurity K. Okay. It didn't even -- yeah,</p> | <p style="text-align: right;">Page 121</p> <p>1 We don't have to go to that, 2 actually. We're going to go to the 3 next document. Oh, you have it. Oh, 4 you know what? You put it up. You're 5 so quick, I can't waste that effort. 6 (Whereupon, Exhibit Number 7 ZHP-300 was marked for 8 identification.)</p> <p>9 BY MR. SLATER:</p> <p>10 Q. On the screen is ZHP02336432, 11 which is a summary of patents for a patent 12 search. And I can tell you based on the 13 metadata this was modified May 23, 2014. 14 That's what the metadata shows, 15 okay?</p> <p>16 A. Okay.</p> <p>17 Q. And if we go to the second page 18 of this document, the bottom of the page, 19 number 4, you can see that this is a 20 discussion of the same patent you see that 21 we've been talking about.</p> <p>22 Do you see that? Same number, 23 CN 103613558. Do you see that?</p> <p>24 A. Where? I'm sorry. Where</p> |

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| <p>1 exactly the number?</p> <p>2 Q. Right in the middle of the</p> <p>3 page. I mean right in the middle of the</p> <p>4 "From" section.</p> <p>5 A. Oh, yeah, yeah, yeah. Okay,</p> <p>6 yeah. I saw that, mm-hmm.</p> <p>7 Q. And this document, which was</p> <p>8 compiled in 2014 within ZHP, at the very end</p> <p>9 of that description says, "The method</p> <p>10 inhibits the generation of valsartan impurity</p> <p>11 K and other impurities hard to treat, so as</p> <p>12 to yield high-purity valsartan."</p> <p>13 Do you see that?</p> <p>14 MR. GALLAGHER: Objection.</p> <p>15 Foundation, and calls for speculation.</p> <p>16 A. I'm sorry, where the language?</p> <p>17 BY MR. SLATER:</p> <p>18 Q. The last sentence.</p> <p>19 A. Last sentence, "and other</p> <p>20 impurities hard to treat so as to" -- okay,</p> <p>21 yeah.</p> <p>22 Q. So at the very least, ZHP was</p> <p>23 aware, at least as of 2014, that there were</p> <p>24 other companies out there trying to eliminate</p> | <p>Page 122</p> <p>1 MR. SLATER: We can take a</p> <p>2 break now, yes.</p> <p>3 Go off the record then.</p> <p>4 THE VIDEOGRAPHER: The time</p> <p>5 right now is 9:24 a.m., and we're off</p> <p>6 the record.</p> <p>7 (Whereupon, a recess was</p> <p>8 taken.)</p> <p>9 (Whereupon, Exhibit Number</p> <p>10 ZHP-301 was marked for</p> <p>11 identification.)</p> <p>12 THE VIDEOGRAPHER: The time</p> <p>13 right now is 9:43 a.m. We're back on</p> <p>14 the record.</p> <p>15 BY MR. SLATER:</p> <p>16 Q. On the screen we have</p> <p>17 Exhibit 301, an e-mail from December 22,</p> <p>18 2018.</p> <p>19 Do you see that?</p> <p>20 A. Yes, mm-hmm.</p> <p>21 MR. GALLAGHER: Adam, is there</p> <p>22 an English language version of this</p> <p>23 document?</p> <p>24 MR. SLATER: That's a good</p> |
| <p>Page 123</p> <p>1 the quality problem created by having</p> <p>2 nitrosamines yielded through sodium nitrite</p> <p>3 quenching.</p> <p>4 Your company would have been</p> <p>5 aware that others were doing that, correct?</p> <p>6 MR. GALLAGHER: Objection.</p> <p>7 Foundation, and mischaracterizes the</p> <p>8 document and the testimony.</p> <p>9 A. It looks like somebody in the</p> <p>10 company, yeah, aware of this patent. But</p> <p>11 again, you know, this patent, as I said, is</p> <p>12 focused on impurity K.</p> <p>13 MR. SLATER: All right. The</p> <p>14 next document I have is probably going</p> <p>15 to take a little while, and I think</p> <p>16 I've been going about an hour. I'm</p> <p>17 happy to keep going. I'm going to</p> <p>18 need 15, 20 minutes at least for the</p> <p>19 next document. So you tell me,</p> <p>20 Patrick.</p> <p>21 MR. GALLAGHER: Dr. Li, it's</p> <p>22 really up to you. Do you want to take</p> <p>23 a break now, or do you want to go for</p> <p>24 another 15 minutes?</p> | <p>Page 125</p> <p>1 question. I don't know.</p> <p>2 Let's go off for a second. If</p> <p>3 there isn't, we'll create one right</p> <p>4 now.</p> <p>5 THE VIDEOGRAPHER: Off the</p> <p>6 record?</p> <p>7 MR. SLATER: Yes.</p> <p>8 THE VIDEOGRAPHER: The time</p> <p>9 right now is 9:44 a.m. We're off the</p> <p>10 record.</p> <p>11 (Off the record discussion.)</p> <p>12 (Whereupon, Exhibit Number</p> <p>13 ZHP-302 was marked for</p> <p>14 identification.)</p> <p>15 THE VIDEOGRAPHER: The time</p> <p>16 right now is 9:44 a.m. We're back on</p> <p>17 the record.</p> <p>18 BY MR. SLATER:</p> <p>19 Q. Looking now at this e-mail --</p> <p>20 rephrase.</p> <p>21 Looking at Exhibit 301, it's an</p> <p>22 e-mail that was sent to you and a few other</p> <p>23 people on December 22, 2018, is that correct?</p> <p>24 A. Yes.</p> |

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| <p style="text-align: right;">Page 126</p> <p>1 Q. Who was the e-mail written by? 2 A. Also from Mr. Lin. 3 Q. The same person who wrote that 4 e-mail of July 27, 2017 that we went through 5 earlier? 6 A. Mm-hmm. 7 Q. And he writes to yourself, and 8 who else is copied? Who else was this 9 written to? 10 A. Mr., you know, Zhu and Chen, 11 Chen Wenbin, yeah. 12 Q. Who are those people? Let's 13 take them one at a time, if you could, 14 please. 15 A. These two, Mr. Zhu and also 16 Mr. Chen, Mr. Zhu is actually my direct 17 report. 18 Q. He reports to you? 19 A. Yes. 20 Q. What's his title? 21 A. He is -- the title is the 22 director for CEMAT, yeah. Analytical -- 23 yeah. 24 Q. I'm sorry. You said</p> | <p style="text-align: right;">Page 128</p> <p>1 structural confirmations, and seven 2 genotoxicity assessments. I hope to 3 communicate with you and find a way to 4 shorten the report review cycle, thank you." 5 Did I read that in a fairly 6 accurate way? 7 A. Yes. 8 Q. And it was signed by Jinsheng 9 Lin at CEMAT, December 22, 2018, correct? 10 A. Yes. 11 MR. SLATER: Let's now go to 12 the attachment, which is the summary 13 of the CEMAT projects with a long 14 report review cycle. 15 THE WITNESS: Okay. 16 MR. SLATER: And that will be 17 Exhibit 302. 18 THE STENOGRAPHER: I think it's 19 303. 302 was the English version. 20 303. 21 MR. SLATER: Thank you. 22 (Whereupon, Exhibit Number 23 ZHP-303 was marked for 24 identification.)</p> |
| <p style="text-align: right;">Page 127</p> <p>1 "analytical" -- 2 A. It should be director of 3 analytical chemistry or something like that, 4 or just, you know, director of analysis, 5 yeah. In Chinese we call (speaking Chinese). 6 Q. And the other person, Mr. Chen, 7 who is that? 8 A. He is under Mr. Zhu. He is the 9 associate -- yeah, should be the associate 10 director, yeah. 11 Q. And tell me if I understand 12 what this e-mail is saying. It has -- first 13 of all, it has an attachment, which we're 14 going to get to in a moment. 15 It is a summary of CEMAT 16 projects with a long report review cycle. 17 Do I understand that? 18 A. Right. Right. 19 Q. The e-mail reads -- rephrase. 20 The e-mail reads, "Mr. Li: 21 Attached please find the summary of 27 recent 22 projects with a report review cycle of more 23 than two months, including 16 impurity 24 studies, one solid-state analysis, three</p> | <p style="text-align: right;">Page 129</p> <p>1 A. Could you enlarge? It's really 2 difficult to see from my end. 3 BY MR. SLATER: 4 Q. We're going to when we scroll 5 up to it. 6 MR. SLATER: But I also -- 7 Patrick, if you'd like, I think we 8 have an English version of this 9 machine translated, is that correct? 10 MR. GALLAGHER: That would be 11 awesome if you do. 12 MR. SLATER: So we'll load that 13 up before I ask any questions. 14 Let me know, Cheryll, when it's 15 been loaded. 16 MR. GALLAGHER: There it is. 17 You're good to go. 18 (Whereupon, Exhibit Number 19 ZHP-304 was marked for 20 identification.) 21 MR. SLATER: So looking now at 22 this spreadsheet, let's go, if we 23 could, to Tab 1.3, Row 53. Perfect. 24 Scroll down a millimeter. Do we have</p> |

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| <p>1 the top of 53?</p> <p>2 Sorry, I shouldn't have made</p> <p>3 you do it.</p> <p>4 A. Go the other way. Could you</p> <p>5 make it bigger?</p> <p>6 BY MR. SLATER:</p> <p>7 Q. We'll make it bigger and work</p> <p>8 our way down?</p> <p>9 A. Could you make it even bigger?</p> <p>10 MS. CALDERON: Give me one</p> <p>11 second. I'm working on it.</p> <p>12 THE WITNESS: Okay.</p> <p>13 MR. SLATER: Just make it</p> <p>14 bigger and then we'll scroll through</p> <p>15 it as we go, so you don't have to try</p> <p>16 to fit the whole thing on one page.</p> <p>17 Make it nice and big. There we go.</p> <p>18 MS. CALDERON: Sorry.</p> <p>19 MR. SLATER: Don't worry about</p> <p>20 it. No one else can do it.</p> <p>21 MS. CALDERON: Obviously I</p> <p>22 can't either.</p> <p>23 MR. SLATER: Keep going. You</p> <p>24 got it. You're going slowly down.</p> | <p>Page 130</p> <p>1 Do you see that?</p> <p>2 A. I'm sorry, where?</p> <p>3 Q. Where we just read. It says,</p> <p>4 "The project was authorized by the technology</p> <p>5 department of Chuannan in Plant 1."</p> <p>6 A. Which line?</p> <p>7 Q. Right after I just read about</p> <p>8 "no longer updated in May" in red.</p> <p>9 A. Wait a second. Oh, the red,</p> <p>10 okay. Yeah. Yeah, they actually, yeah, ask</p> <p>11 CEMAT to do the investigation, yes.</p> <p>12 Q. So how does that work? You</p> <p>13 have Chuannan and Xunqiao, if I'm pronouncing</p> <p>14 those right, if they have something like an</p> <p>15 impurity investigation they need to do, they</p> <p>16 ask CEMAT to do that work for them?</p> <p>17 A. Well, sometimes they will do by</p> <p>18 themselves along with, you know, Chuannan QC.</p> <p>19 But if they cannot resolve, yeah, they</p> <p>20 usually send it to us.</p> <p>21 Q. And then I'm going to read a</p> <p>22 little further. It says, "Due to the</p> <p>23 incomplete quenching of sodium azide caused</p> <p>24 by the separate treatment of irbesartan</p> |
| <p>Page 131</p> <p>1 Now you're at 172 again.</p> <p>2 MS. CALDERON: That's it.</p> <p>3 MR. SLATER: Thank you.</p> <p>4 BY MR. SLATER:</p> <p>5 Q. Okay. Looking now in Box 53,</p> <p>6 at the top it talks about Investigation on</p> <p>7 the RT 26-minute impurity in irbesartan crude</p> <p>8 product.</p> <p>9 Do you see that?</p> <p>10 A. Mm-hmm.</p> <p>11 Q. It says the responsible person</p> <p>12 was Tianpei Huang, new project in July 2017,</p> <p>13 completed in April and no longer updated in</p> <p>14 May.</p> <p>15 Do you see that?</p> <p>16 A. Mm-hmm.</p> <p>17 Q. And again, who is Mr. Huang?</p> <p>18 A. She is one of the analysts at</p> <p>19 the time.</p> <p>20 Q. She was an analyst at CEMAT?</p> <p>21 A. Yes. She was, actually.</p> <p>22 Q. It says, "The project was</p> <p>23 authorized by the Technology Department of</p> <p>24 Chuannan in Plant 1."</p> | <p>Page 131</p> <p>1 sodium azide wastewater, there is a frequent</p> <p>2 occurrence of muffled explosion in the</p> <p>3 production process, so the technology</p> <p>4 department carried out the technical</p> <p>5 improvement by which the sodium azide</p> <p>6 quenching takes place in the unstratified</p> <p>7 step in the crude irbesartan process."</p> <p>8 Do I have that correct?</p> <p>9 MR. GALLAGHER: I'm going to</p> <p>10 object to this as outside the scope.</p> <p>11 But please answer to the extent</p> <p>12 you know and can.</p> <p>13 A. Yeah.</p> <p>14 BY MR. SLATER:</p> <p>15 Q. It then continues -- and, by</p> <p>16 the way, when it talks about the</p> <p>17 "unstratified step in the crude irbesartan</p> <p>18 process," what does that refer to,</p> <p>19 "unstratified," in that context?</p> <p>20 A. Unstratified. I'm sorry, I</p> <p>21 don't understand exactly what you mean by</p> <p>22 "unstratified."</p> <p>23 Q. Well, I'll ask the question</p> <p>24 differently then. Let me just continue.</p> |

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| <p>1 It continues, "However, after 2 the improvement there is an unknown impurity 3 of about 0.5 percent at 26 minutes in the 4 crude irbesartan, and the structure of this 5 impurity needs to be investigated."</p> <p>6 Do you see that?</p> <p>7 MR. GALLAGHER: Again, I'm 8 going to object as outside the scope.</p> <p>9 But please answer to the extent 10 you know and can.</p> <p>11 A. So could you point out exactly, 12 like, which line? I'm sorry. Because, you 13 know, the English and the Chinese, you know, 14 version --</p> <p>15 BY MR. SLATER:</p> <p>16 Q. Can I point out exactly what 17 line? I'm not going to be able to point out 18 exactly what line. How about this is all 19 above the "July Process Update."</p> <p>20 Do you see that?</p> <p>21 A. Let me -- how about let me -- 22 you know, let me take a little bit of time 23 and read this through, okay?</p> <p>24 Q. Sure. Let's go off the timer,</p> | <p>Page 134</p> <p>1 BY MR. SLATER: 2 Q. And you said "correct," right, 3 Dr. Li? 4 A. I'm sorry, say that again? 5 Q. What they're discussing in this 6 Box 53 is a study, a research project that 7 was being performed that followed from that 8 e-mail that Jinsheng Lin wrote that we talked 9 about a few minutes earlier, correct? 10 A. It looks like. 11 Q. Then there's process updates 12 going forward. And it shows, for example, in 13 July, in part it says that "Based on the 14 process of generation, the impurity should be 15 a nitroso compound in irbesartan. The 16 degradation experiment is currently being 17 carried out, and subsequently the sample will 18 be prepared." 19 That's correct in part, right? 20 A. Mm-hmm. 21 Q. And when they refer to "a 22 nitroso compound," we're talking about a 23 nitrosamine, correct? 24 A. This nitrosamine is the nitroso</p> |
| <p>Page 135</p> <p>1 and you can take a look, and then we'll walk 2 through it a little more generally. That's a 3 good idea?</p> <p>4 A. Okay.</p> <p>5 MR. SLATER: Stay on the 6 record, off the clock. No problem.</p> <p>7 (Witness reviewing document.)</p> <p>8 THE WITNESS: Okay. I 9 basically read through. We can go 10 ahead.</p> <p>11 BY MR. SLATER:</p> <p>12 Q. I'll start over.</p> <p>13 In this Box 53, you can see 14 there's a discussion of the investigation of 15 the impurity in the irbesartan crude product 16 that we were talking about per that prior 17 e-mail that Jinsheng Lin wrote, correct?</p> <p>18 MR. GALLAGHER: I'm going to 19 object to the questioning about this 20 box as outside the scope so I don't 21 have to keep repeating it.</p> <p>22 MR. SLATER: That's fine.</p> <p>23 You've got that objection.</p> <p>24 ///</p> | <p>Page 137</p> <p>1 compound on the irbesartan, okay. It's very 2 specific.</p> <p>3 Q. Then there's an August process 4 update in August 2017 that said, "The forced 5 degradation experiment proved that the 6 impurity was a result of the reaction of 7 irbesartan with sodium nitrite and 8 hydrochloric acid. At present, the impurity 9 has been prepared by thin layer 10 chromatography."</p> <p>11 Do I have that correct?</p> <p>12 A. Yes.</p> <p>13 Q. Then in September there's a 14 process update that says, "The impurity 15 standard production has been separated and 16 was sent to Dan Li for nuclear magnetic 17 resonance."</p> <p>18 My first question is, who is 19 Dan Li?</p> <p>20 A. She is a person specializing in 21 NMR structure characterization, or nuclear 22 magnetic resonance.</p> <p>23 Q. And what's the purpose of that 24 test in this context? What would that be</p> |

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| <p>1 trying to show?</p> <p>2 A. Trying to elucidate, you know,</p> <p>3 the structure.</p> <p>4 Q. The structure of the</p> <p>5 nitrosamine?</p> <p>6 A. No, that particular, you know,</p> <p>7 nitroso compound with irbesartan.</p> <p>8 Q. And then it points out that</p> <p>9 there was a malfunction of the equipment so</p> <p>10 the test couldn't start at that time.</p> <p>11 Do I have that right?</p> <p>12 A. Yes.</p> <p>13 Q. And then if we go forward,</p> <p>14 there are updates in October and November,</p> <p>15 and then in December it says the research</p> <p>16 report is being completed, correct?</p> <p>17 A. Yes.</p> <p>18 Q. And then in January, now</p> <p>19 January 2018, it says that the research</p> <p>20 report was completed pending review, correct?</p> <p>21 A. Correct.</p> <p>22 Q. Then we go forward into March.</p> <p>23 There's no update in March, right? Just</p> <p>24 says, "No update"?</p> | <p>Page 138</p> <p>1 Do you have any idea where we</p> <p>2 would look to find that report?</p> <p>3 A. I don't -- I don't recall. You</p> <p>4 know, I don't even recall this particular</p> <p>5 discussion. I mean, you know, this so long,</p> <p>6 you know, you can see there's so many</p> <p>7 projects, you know, ongoing. So I really</p> <p>8 don't, you know, remember the specifics.</p> <p>9 Q. And, again, this says that the</p> <p>10 reason why the research report was not to be</p> <p>11 issued and not to be updated any further was</p> <p>12 after discussing with you, you had pointed</p> <p>13 out that the project involves an impurity</p> <p>14 that is sensitive.</p> <p>15 That's what the document shows,</p> <p>16 correct?</p> <p>17 A. It looks like so.</p> <p>18 Q. And reading that doesn't</p> <p>19 refresh your recollection of telling your</p> <p>20 team to -- not to do anything further with</p> <p>21 the report and not to issue it? You don't</p> <p>22 recall that?</p> <p>23 A. As I said, I don't remember,</p> <p>24 you know, the specifics. Maybe the reason</p> |
| <p>Page 139</p> <p>1 A. Right.</p> <p>2 Q. And then in April it says,</p> <p>3 "After discussing with Mr. Li, as the project</p> <p>4 involves an impurity that is sensitive so no</p> <p>5 research report will be issued and no further</p> <p>6 updates will be made." Correct?</p> <p>7 A. It looks like so.</p> <p>8 Q. So you instructed that this</p> <p>9 research project not go forward any further</p> <p>10 and no report to be issued, as documented</p> <p>11 here, correct?</p> <p>12 MR. GALLAGHER: Objection.</p> <p>13 Foundation, and assumes facts.</p> <p>14 BY MR. SLATER:</p> <p>15 Q. That is what it says, correct?</p> <p>16 A. Based upon what it says, yeah,</p> <p>17 it looks like so.</p> <p>18 Q. Do you know where that report</p> <p>19 is?</p> <p>20 A. I don't recall.</p> <p>21 Q. Where would we look to find</p> <p>22 that report? Because I can represent we've</p> <p>23 been looking for it and have been unable to</p> <p>24 find it.</p> | <p>Page 141</p> <p>1 is, you know, you know, I can -- maybe the</p> <p>2 reason is basically this is not, you know,</p> <p>3 relevant to a real process, right? Because</p> <p>4 this is a trial and, you know, they -- you</p> <p>5 know, during the trial they change the way of</p> <p>6 the -- you know, of the quenching, right?</p> <p>7 So, yeah, so basically, you</p> <p>8 know, you know, this compound would not be</p> <p>9 present in a normal registered, you know, the</p> <p>10 process.</p> <p>11 So maybe I want to just, you</p> <p>12 know, ask them to -- because issuing this</p> <p>13 could be -- could have caused some confusion.</p> <p>14 You know, people may confuse the presence of</p> <p>15 this particular impurity with the registered,</p> <p>16 you know, process.</p> <p>17 Q. You testified a few moments ago</p> <p>18 you don't recall this at all. So everything</p> <p>19 you're telling me about what might have</p> <p>20 happened --</p> <p>21 A. This is what I'm trying to --</p> <p>22 you know, it's a -- you know, what I'm trying</p> <p>23 to, you know, you know, reconfigure, you</p> <p>24 know, a possible scenario. You know, this is</p> |

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| <p style="text-align: right;">Page 142</p> <p>1 not, you know, you know, what really may 2 happen. You know what I'm saying? It's 3 just, you know, give some, you know, 4 speculation, you know what I'm saying?</p> <p>5 But, yeah, definitely I don't 6 remember exactly, you know, what I had said 7 during that particular time. Okay?</p> <p>8 Q. Well, this document certainly 9 sets forth that you were concerned at the 10 time that the impurity was a sensitive 11 impurity, and that would be talking about a 12 nitrosamine impurity; that you were concerned 13 about that, right?</p> <p>14 A. Well, as I said, you know, you 15 know, the possible reason, right? As I said, 16 it's a possible reason.</p> <p>17 You know, maybe I wanted to 18 avoid, you know, the confusion of an 19 impurity, you know, from this trial, you 20 know, process, with an impurity from the real 21 ones. Okay.</p> <p>22 But again, look at this 23 particular, you know, impurity, you know, 24 this particular impurity itself, you know, if</p> | <p style="text-align: right;">Page 144</p> <p>1 to now, you know, for those, you know, like 2 large molecule and nitroso compound, 3 particularly with substituents surrounding 4 the, you know, nitroso compound, if they are 5 big, typically you tend to have this kind of 6 a, you know, nitroso compound to be Ames 7 negative.</p> <p>8 Q. At this time, as documented -- 9 well, rephrase. I want to just go over a 10 couple of basic facts that we have here, 11 okay?</p> <p>12 A. Mm-hmm.</p> <p>13 Q. One of the things we know is 14 that this demonstrates, as did the e-mail we 15 went through before, that ZHP was aware that 16 the sodium nitrite quenching was creating 17 nitrosamine impurities. That you knew.</p> <p>18 A. We knew based upon this 19 document --</p> <p>20 MR. GALLAGHER: Objection. 21 Misstates the testimony.</p> <p>22 Go ahead. Go ahead.</p> <p>23 A. I'm sorry.</p> <p>24 Based upon document, yeah, we</p> |
| <p style="text-align: right;">Page 143</p> <p>1 you look at a structure, it's not a typical 2 N-nitroso compound, okay?</p> <p>3 And based upon everything that 4 we have know, you know, for now, you know, 5 you know, if we were to do an Ames test on 6 this particular, you know, nitroso compound 7 of irbesartan, I would say, you know, you 8 know, you know, a reasonable projection 9 was -- you know, would be the Ames would very 10 be likely be negative, okay, you know, based 11 upon everything, you know, that we know by 12 now, you know, based upon what they call a 13 QSAR, quantitative structure-activity 14 analysis.</p> <p>15 You know, I mean, it's the same 16 thing like impurity K, right? Because, you 17 know, see, the reason is why those compounds 18 may be Ames negative is because you have 19 to -- you know, when you look at the activity 20 of a compound, you know, one of the things 21 you also have to look at is the serial 22 chemistry, right?</p> <p>23 So based upon the knowledge 24 that we have, you know, gained, you know, up</p> | <p style="text-align: right;">Page 145</p> <p>1 knew specifically the nitroso compound of 2 irbesartan, okay. And also, irbesartan is 3 the main ingredient of that particular 4 reaction.</p> <p>5 Q. And you also knew per the 6 e-mail we went through that NDMA occurs in 7 valsartan when it was quenched with sodium 8 nitrite. That was known as of July 2017. 9 That's why that was stated by Jen Sheng Lin, 10 correct?</p> <p>11 MR. GALLAGHER: Objection. 12 Mischaracterizes.</p> <p>13 A. As I told you, you know, you 14 know, for that e-mail, you know, I do not 15 recall. Now looking back, you know, you 16 know, basically, as I said, anything about, 17 you know, you know, valsartan is huge 18 speculation because, you know, you know, the 19 data that's shown here is specifically 20 regarding to irbesartan.</p> <p>21 BY MR. SLATER:</p> <p>22 Q. Well, why don't we do this. 23 Let's just -- in fairness, let's go back to 24 the e-mail to get ourselves oriented here.</p> |

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| <p>1 A. Okay.</p> <p>2 Q. And that was Exhibit -- gosh, I</p> <p>3 lost track of which exhibit it was. Cheryll</p> <p>4 knows. She's going to find it.</p> <p>5 MS. CALDERON: Do you want me</p> <p>6 to put it up?</p> <p>7 MR. SLATER: I would, please.</p> <p>8 And if we can clarify for the</p> <p>9 record what exhibit number that was,</p> <p>10 I'll write it on here so I won't</p> <p>11 forget again.</p> <p>12 MS. CALDERON: Hang on one</p> <p>13 second. It's 295.</p> <p>14 MR. SLATER: Great. Thank you.</p> <p>15 And let's go to the top of the second</p> <p>16 page again. Just -- okay.</p> <p>17 Q. Looking now at the top of the</p> <p>18 second page of Exhibit 295, which was an</p> <p>19 e-mail dated July 27, 2017, from Jinsheng Lin</p> <p>20 in your CEMAT facility, he pointed out that</p> <p>21 what was being seen with the irbesartan is</p> <p>22 similar to the NDMA that occurs in valsartan</p> <p>23 when quenched with sodium nitrite.</p> <p>24 That's part of what Jinsheng</p> | <p>Page 146</p> <p>1 MR. GALLAGHER: I guess I want</p> <p>2 to clarify. Are you looking at the</p> <p>3 English language translation, or are</p> <p>4 you looking at the actual Chinese</p> <p>5 language document?</p> <p>6 MR. SLATER: Well, I don't know</p> <p>7 why that matters, honestly. You have</p> <p>8 them.</p> <p>9 MR. GALLAGHER: I don't see any</p> <p>10 semicolons in the Chinese language</p> <p>11 document.</p> <p>12 THE WITNESS: Yeah, in the</p> <p>13 Chinese language, it's just a regular</p> <p>14 comma. Yeah, it's a comma.</p> <p>15 MR. SLATER: Okay. There's a</p> <p>16 semicolon objection. I'm going to fix</p> <p>17 it. I'll start a new question.</p> <p>18 BY MR. SLATER:</p> <p>19 Q. After pointing out what we just</p> <p>20 established had to do with irbesartan,</p> <p>21 Mr. Lin then says, "It is similar to the NDMA</p> <p>22 that occurs in valsartan when quenched with</p> <p>23 sodium nitrite."</p> <p>24 That's what he says in this</p> |
| <p>Page 147</p> <p>1 Lin said in that e-mail, correct?</p> <p>2 A. Well, in his -- see, in the</p> <p>3 beginning of the sentence, he said, you know,</p> <p>4 it's likely, you know, or most likely, right?</p> <p>5 So -- yeah, so that's a speculation.</p> <p>6 BY MR. SLATER:</p> <p>7 Q. Well, actually, let's walk</p> <p>8 through it then.</p> <p>9 What he said was, "Through the</p> <p>10 secondary mass spectrometry analysis, it can</p> <p>11 be inferred that the extra NO substituent is</p> <p>12 in the cyclic compound fragment, and it is</p> <p>13 very likely that it is an N-NO compound."</p> <p>14 That's talking about what's</p> <p>15 being seen in the irbesartan, correct?</p> <p>16 A. Yes.</p> <p>17 Q. Then after the semicolon he</p> <p>18 states, "It is similar to the NDMA that</p> <p>19 occurs in valsartan when quenched with sodium</p> <p>20 nitrite," correct?</p> <p>21 MR. GALLAGHER: Objection.</p> <p>22 Mischaracterizes.</p> <p>23 BY MR. SLATER:</p> <p>24 Q. That's what it says, right?</p> | <p>Page 149</p> <p>1 document July 27, 2017, correct?</p> <p>2 A. Yes.</p> <p>3 Q. Do you know how long your</p> <p>4 company knew that NDMA occurs in valsartan</p> <p>5 when quenched with sodium nitrite, how long</p> <p>6 before July of 2017 people in your company</p> <p>7 knew that?</p> <p>8 A. I don't know. Looks like only</p> <p>9 he knows at the time.</p> <p>10 Q. He was the one who did the</p> <p>11 patent review, right, that we went through</p> <p>12 before, going back to 2014 on this, right?</p> <p>13 A. Mm-hmm.</p> <p>14 Q. So at least this person who you</p> <p>15 told us was a, and remains an important</p> <p>16 person in your organization was looking at</p> <p>17 this issue going back to 2014. We've</p> <p>18 established that with the document, correct?</p> <p>19 MR. GALLAGHER: Objection.</p> <p>20 Mischaracterizes the testimony.</p> <p>21 But please answer.</p> <p>22 A. Yes.</p> <p>23 BY MR. SLATER:</p> <p>24 Q. And we also know that he was</p> |

| Page 150 | Page 152 |
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| <p>1 concerned -- rephrase. 2 And we also know that he was 3 concerned -- 4 MR. SLATER: If we scroll down 5 to the second-to-last paragraph on 6 this page. 7 Q. -- that with regard to the 8 irbesartan, if it was in a nitrosamine 9 compound, "then its toxicity will be very 10 strong, and there will be an extremely high 11 GMP risk." 12 That's what he says, right? 13 MR. GALLAGHER: Objection. 14 Outside the scope. 15 A. Again, as I said, you know, 16 he's making speculation outside of his 17 expertise. 18 BY MR. SLATER: 19 Q. Well, what he's doing is 20 analyzing what we know from earlier testimony 21 you gave was the root cause for the NDMA 22 formation which was caused by the sodium 23 nitrite, correct? 24 A. Part of the -- yes.</p> | <p>1 know, I don't recall, you know, specifically 2 looking through this e-mail. 3 Q. And, in fact, the right thing 4 to do at this point when you're -- rephrase. 5 The right thing to do -- as 6 soon as your company knew that nitrosamines 7 were being yielded by the sodium nitrite 8 quenching, the right thing to do would have 9 been to stop production and optimize the 10 process at that time and reveal to world 11 regulatory authorities this problem, right? 12 That would have been the right 13 thing to do when your company discovered this 14 internally, right? 15 MR. GALLAGHER: Objection. 16 Vague, outside the scope, and calls 17 for speculation. 18 A. You know, I don't know, or I 19 didn't know at the time how far, you know, 20 you know, this went through, right. 21 He sent to those people. I 22 didn't know, and I do not know, you know, how 23 those people -- their response. They may 24 ignore or they may think this -- you know,</p> |
| Page 151 | Page 153 |
| <p>1 Q. So he was correct that the 2 sodium nitrite quenching creating 3 nitrosamines was a serious GMP problem. 4 He was correct about that, 5 right? 6 MR. GALLAGHER: Objection. 7 A. That's speculation. 8 BY MR. SLATER: 9 Q. Well, if you want to call it 10 speculation, that's fine. But it was 11 confirmed, and that's the root cause analysis 12 that you've already testified to that your 13 company came to, right? 14 A. After, you know -- yeah, after 15 the events, yes. 16 Q. Well, that's what was disclosed 17 after the events, but this e-mail shows that 18 people in your company knew about this, 19 including yourself when you got this e-mail, 20 in July of 2017, right? 21 A. As I said, you know, you know, 22 I am -- you know, I was under this, but I -- 23 you know, as I said, I didn't have time to, 24 you know, go through everything and, you</p> | <p>1 maybe he's -- Mr. Lin's speculation. 2 So, basically, it looks like it 3 didn't, you know, go far. 4 BY MR. SLATER: 5 Q. In retrospect, it's too bad it 6 didn't go far because the right thing to do 7 would have been to disclose this to the 8 regulatory authorities and stop production, 9 right? 10 MR. GALLAGHER: Objection. 11 Vague, outside the scope, calls for 12 speculation, and asked and answered. 13 THE WITNESS: I mean, do I need 14 to answer? 15 MR. GALLAGHER: Answer to the 16 extent -- you know, to the extent you 17 can. 18 THE WITNESS: Sure. 19 I mean basically, you know, for 20 me it's the same thing. I mean, 21 retrospectively, you know, you know, 22 it might be, but at the time people 23 may thought, you know, he just, you 24 know, making his speculations and --</p> |

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| <p style="text-align: right;">Page 154</p> <p>1 BY MR. SLATER:</p> <p>2 Q. Well, looking at the last</p> <p>3 sentence, he said -- rephrase.</p> <p>4 Looking at the last paragraph,</p> <p>5 he said in part, after looking at the patent</p> <p>6 going back to 2013 and 2014 from one of your</p> <p>7 competitors, that that indicated that other</p> <p>8 companies had paid attention to the quality</p> <p>9 problem very early on, and that quality</p> <p>10 problem is sodium nitrite quenching creating</p> <p>11 nitrosamines in your company's sartans,</p> <p>12 including valsartan, correct?</p> <p>13 That's what we've established,</p> <p>14 correct?</p> <p>15 A. Well, again --</p> <p>16 MR. GALLAGHER: Objection.</p> <p>17 Mischaracterizes the testimony and the</p> <p>18 documents.</p> <p>19 A. Right. I mean, you know, once</p> <p>20 again, that N-nitroso compound, right,</p> <p>21 specified in the patent, you know, was, you</p> <p>22 know, impurity K, okay.</p> <p>23 So this impurity K, as I said,</p> <p>24 has been controlled as a regular impurity,</p> | <p style="text-align: right;">Page 156</p> <p>1 MR. GALLAGHER: Objection.</p> <p>2 Outside the scope.</p> <p>3 To the extent you know</p> <p>4 personally, you can answer.</p> <p>5 A. I do not know what FDA's, you</p> <p>6 know, you know, specific requirement at this</p> <p>7 time, okay? But in one of the communications</p> <p>8 I think came, you know, from FDA last year,</p> <p>9 they asked us to do some further in vivo</p> <p>10 animal study on the impurity K, okay, which</p> <p>11 we did.</p> <p>12 We did a particular in vivo,</p> <p>13 you know, enrolled in animal studies</p> <p>14 according to the principle of, you know, ICH</p> <p>15 M7, and we submitted this, you know, you</p> <p>16 know, proposal back to FDA.</p> <p>17 I think our proposal was to --</p> <p>18 you know, essentially there is no need to</p> <p>19 control at such low level. It would be</p> <p>20 controlled, you know, based upon our current,</p> <p>21 you know, process.</p> <p>22 I don't remember exactly, you</p> <p>23 know, what specific, you know, specification</p> <p>24 that we'd propose. It could be like several</p> |
| <p style="text-align: right;">Page 155</p> <p>1 okay? Its level is 1,000 ppm.</p> <p>2 BY MR. SLATER:</p> <p>3 Q. Is that what you believe the</p> <p>4 FDA permitted your company -- rephrase.</p> <p>5 Is that your understanding of</p> <p>6 the FDA's position on that impurity?</p> <p>7 MR. GALLAGHER: Objection.</p> <p>8 Outside the scope.</p> <p>9 THE WITNESS: I'm sorry. Go</p> <p>10 ahead.</p> <p>11 MR. GALLAGHER: Objection.</p> <p>12 Outside the scope.</p> <p>13 To the extent you know, please</p> <p>14 answer.</p> <p>15 A. Okay. I mean, FDA is well</p> <p>16 aware of the impurity K is Ames negative,</p> <p>17 okay.</p> <p>18 BY MR. SLATER:</p> <p>19 Q. I'm just asking, do you know</p> <p>20 what the FDA's position was on the impurity</p> <p>21 K? Do you know whether they thought it could</p> <p>22 be handled as a regular impurity or whether</p> <p>23 they said it had to be limited to 0.3 ppm?</p> <p>24 Do you know?</p> | <p style="text-align: right;">Page 157</p> <p>1 hundredths of ppm.</p> <p>2 BY MR. SLATER:</p> <p>3 Q. Let's be clear. You're talking</p> <p>4 about impurity K, right?</p> <p>5 A. Right.</p> <p>6 Q. You're not talking about NDMA</p> <p>7 or NDEA, right?</p> <p>8 A. No.</p> <p>9 Q. Because those would never be</p> <p>10 acceptable at regular levels, right?</p> <p>11 A. Retrospectively we know, yes.</p> <p>12 Q. And you knew that the FDA</p> <p>13 guidances and the European guidances all said</p> <p>14 that nitrosamine compounds needed to be</p> <p>15 excepted from the threshold approach because</p> <p>16 they're considered so dangerous, they</p> <p>17 couldn't even be allowed to be included based</p> <p>18 on the standard threshold approach.</p> <p>19 Were you aware of that?</p> <p>20 MR. GALLAGHER: Objection.</p> <p>21 Outside the scope, and lack of</p> <p>22 foundation.</p> <p>23 A. Retrospectively, based upon M7,</p> <p>24 yeah. That's in general. But as I said, you</p> |

| Page 158 | Page 160 |
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| <p>1 know, the European, you know, authority, they 2 specifically had a discussion on impurity K, 3 you know, in which obviously that's after, 4 you know, these events came out.</p> <p>5 And they specifically, you 6 know, you know, at the time at least they 7 allow the original -- it looks like the 8 original Novartis specification at 1,000 ppm.</p> <p>9 BY MR. SLATER:</p> <p>10 Q. Let's come back now to this 11 e-mail where I was reading with you, where 12 Jinsheng Lin said, "This indicates that other 13 companies have paid attention to the quality 14 problem very early on."</p> <p>15 Just to be clear, the quality 16 problem was sodium nitrite quenching creating 17 nitrosamines, correct?</p> <p>18 A. Again, as I said, he's making 19 speculations, and that pattern is 20 specifically talking about impurity K.</p> <p>21 Q. Well, he also talked above 22 about NDMA forming in valsartan when it's 23 quenched with sodium nitrite. He also 24 pointed out that your company knew that as</p> | <p>1 from my sight.</p> <p>2 BY MR. SLATER:</p> <p>3 Q. And slipped through Linda Lin's 4 sight and Peng Dong? All of those, none of 5 them did anything?</p> <p>6 A. That, I don't know. I -- you 7 know, I have no knowledge, you know.</p> <p>8 Q. Do you know why it is that this 9 e-mail, which was sent to Ms. Ge and to Peng 10 Dong and Linda Lin, that it didn't show up in 11 any of their custodial files, and none of 12 them are listed as duplicate custodians on 13 this document?</p> <p>14 Do you know why that happened?</p> <p>15 MR. GALLAGHER: Objection.</p> <p>16 A. I don't know.</p> <p>17 MR. GALLAGHER: Outside the scope.</p> <p>18 BY MR. SLATER:</p> <p>19 Q. You don't know?</p> <p>20 Do you know why the report 21 that's referenced in the spreadsheet that we 22 went through that documents in April of 2018 23 you said, "The report will not be issued and</p> |
| <p>1 well.</p> <p>2 He talked about that, right?</p> <p>3 A. He talked about only he knew.</p> <p>4 I don't know anybody else at that time, you 5 know, before his e-mail.</p> <p>6 Q. When -- well, rephrase.</p> <p>7 When you and Peng Dong and 8 Linda Lin and the others in that e-mail got 9 this e-mail, if that was the first time that 10 you saw that, shouldn't that have been an 11 alarm bell going off in your head and say, 12 "My gosh, there's NDMA forming in our 13 valsartan; this is a major problem"?</p> <p>14 That would have been the 15 appropriate response, right?</p> <p>16 MR. GALLAGHER: Objection.</p> <p>17 Vague.</p> <p>18 A. I mean, retrospectively, you 19 know, you know, if I went through or if 20 Mr. Lin specifically came to me, you know, 21 that might be, you know, the starting of the, 22 you know, of the action time.</p> <p>23 But as again, you know, it 24 looks like this e-mail just slipped through</p> | <p>1 it shouldn't be updated any further due to 2 the sensitivity of this impurity," do you 3 know why that report has never been produced 4 to us?</p> <p>5 MR. GALLAGHER: Objection.</p> <p>6 Outside the scope.</p> <p>7 A. I have no idea.</p> <p>8 BY MR. SLATER:</p> <p>9 Q. One way to try to get that 10 would be to search the custodial files of 11 Dan Li and Tianpei Huang. They might have it 12 in their custodial files, correct?</p> <p>13 MR. GALLAGHER: I'm going to 14 object to these questions as 15 argumentative, they're so far outside 16 the scope.</p> <p>17 Why you would ask Mr. Li about 18 searching documents of other people 19 makes absolutely no sense.</p> <p>20 So, you know, Dr. Li, you can 21 answer to the extent you have any 22 knowledge of this.</p> <p>23 But, Adam, I think you need to 24 move on.</p> |
| Page 159 | Page 161 |

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| <p style="text-align: right;">Page 162</p> <p>1 MR. SLATER: Well, these people 2 work for him, and he knows where they 3 keep their documents and how they keep 4 their files.</p> <p>5 MR. GALLAGHER: Those aren't 6 the questions you're asking.</p> <p>7 A. They are the first-line 8 analysts, okay, and they usually -- you know, 9 they don't talk to me, you know, very often, 10 you know, at my level.</p> <p>11 BY MR. SLATER:</p> <p>12 Q. If that report was destroyed, 13 would that be acceptable in terms of how your 14 department operates?</p> <p>15 A. I don't know whether it's been 16 destroyed or not.</p> <p>17 Q. If it was destroyed, would that 18 be acceptable?</p> <p>19 A. That's a hypothetical question. 20 It may be destroyed or, you know, per 21 company's -- you know, because everyone, you 22 know, company has certain -- as I mentioned, 23 you know, you know, on the company server, if 24 you deleted something, you know, because from</p> | <p style="text-align: right;">Page 164</p> <p>1 documents.</p> <p>2 BY MR. SLATER:</p> <p>3 Q. I'll ask it -- there's an 4 objection. Let me ask a different question, 5 because there's an objection. So I'm going 6 to strive for a better question.</p> <p>7 The -- rephrase.</p> <p>8 Knowing that sodium nitrite 9 quenching in the manufacture of valsartan was 10 an important part of causing nitrosamines to 11 be formed, that was important information, 12 right?</p> <p>13 MR. GALLAGHER: Objection.</p> <p>14 Vague.</p> <p>15 You can answer.</p> <p>16 A. You know, again, that patent 17 specifically talking about impurity K, okay. 18 Anything else, there is no specifics.</p> <p>19 BY MR. SLATER:</p> <p>20 Q. Well, what it talks -- 21 rephrase.</p> <p>22 The patent talks about how to 23 avoid creating nitroso compounds. And that's 24 the way you avoid it, is by not quenching</p> |
| <p style="text-align: right;">Page 163</p> <p>1 time to time your mailbox fill up, and some 2 people, you know, you know, they have -- may 3 have to have it to, you know, very often to 4 delete it, right?</p> <p>5 So after, you know, certain 6 period of the deletion it will be 7 automatically, you know, like, taken from, 8 you know, the company server.</p> <p>9 Q. Let's also talk about -- well, 10 rephrase.</p> <p>11 We talked about the patent, and 12 you spoke about impurity K a bunch of times.</p> <p>13 A. Mm-hmm.</p> <p>14 Q. A very important message in 15 these e-mail and in that patent is that it 16 was figured out, your company knew it and 17 others started to figure it out on the 18 outside, that the way to avoid creating 19 nitrosamine compounds was to not quench with 20 sodium nitrite.</p> <p>21 That's an important lesson 22 that's being discussed here, right?</p> <p>23 MR. GALLAGHER: Objection.</p> <p>24 Mischaracterizes the testimony and the</p> | <p style="text-align: right;">Page 165</p> <p>1 with sodium nitrite, correct?</p> <p>2 A. Again, as I mentioned, every 3 nitroso compound, you know, is different, 4 okay, specifically for the impurity K. Now 5 we know, you know, it's, again, Ames 6 negative.</p> <p>7 So, you know, so do not confuse 8 or replace that, you know, nitroso compound 9 with NDMA.</p> <p>10 I mean, you know, in that 11 patent, as far as, you know, based upon the 12 information that you presented, you know, I 13 don't see so far, you know, in that patent, 14 there's any specific mention of NDMA in that 15 patent.</p> <p>16 Q. No. What there's mention of is 17 that your competitor wanted to eliminate 18 sodium nitrite as the quenching agent and 19 instead used bleach so that it wouldn't form 20 nitrosamines as part of the process, correct?</p> <p>21 A. I mean, again, you know --</p> <p>22 MR. GALLAGHER: Objection.</p> <p>23 A. -- that nitrosamine is not 24 NDMA, okay, is impurity K. So, you know,</p> |

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| <p style="text-align: right;">Page 166</p> <p>1 okay, they are different. 2 BY MR. SLATER: 3 Q. At the very bottom of this 4 page, which is, I think, where we went off on 5 this tangent, but let me bring it back and 6 then we'll move on. 7 At the bottom of this page 8 Jinsheng Lin said, "This indicates that other 9 companies have paid attention to the quality 10 problem very early on. So leaders please pay 11 attention to this issue." 12 That was a warning that you 13 said either slipped through the cracks or was 14 ignored, but it's a warning that should have 15 been listened to, right? 16 MR. GALLAGHER: Objection. 17 Mischaracterizes the testimony, and 18 mischaracterizes the documents. 19 A. I think I already, you know, 20 you know, answered your question before. 21 BY MR. SLATER: 22 Q. Well, in retrospect, you would 23 agree with me that whenever the company knew 24 at some point before July of 2017 that NDMA</p> | <p style="text-align: right;">Page 168</p> <p>1 Vague, calls for speculation, and 2 outside the scope. 3 A. I mean, at a time of point, if 4 someone went through, you know, and if they 5 are like process, you know, people, they 6 probably, you know, as I said, you know, just 7 saw him, you know, just making unrealistic 8 projections. That's my guess. That's my 9 guess. 10 BY MR. SLATER: 11 Q. Well, you're calling it an 12 unrealistic projection. In fact, he was 13 100 percent right. 14 A. No, he is not 100 percent 15 right. As I said, you know, he's making, you 16 know, those things -- as I said, you know, 17 not everything -- by now we know not every 18 nitrosamine is highly toxic, okay? 19 Like impurity K, based upon, 20 you know, everything that we now know, you 21 know, it has been controlled but treated as a 22 regular impurity at 1,000 ppm, you know, that 23 was by Novartis, the original inventor of 24 valsartan.</p> |
| <p style="text-align: right;">Page 167</p> <p>1 was occurring in valsartan when quenched with 2 sodium nitrite, you would agree that as soon 3 as that was known, action should have been 4 taken to stop manufacturing by that process 5 until it could be optimized to prevent NDMA 6 from being created, correct? 7 MR. GALLAGHER: Objection. 8 Vague, calls for speculation, and 9 outside the scope. 10 A. Again, I think I already, you 11 know, answered your question before. I mean, 12 if you wanted me to repeat, you know, I 13 mean... 14 BY MR. SLATER: 15 Q. Well, I'm just asking you 16 simply, would you acknowledge sitting here 17 now -- I'll ask it differently. 18 Do you wish when Jinsheng Lin 19 sent this e-mail in July of 2017 that it 20 hadn't been ignored and it didn't fall 21 through the cracks, and that your company had 22 taken immediate action to stop manufacturing 23 valsartan with sodium nitrite quenching? 24 MR. GALLAGHER: Objection.</p> | <p style="text-align: right;">Page 169</p> <p>1 Q. You're certainly not telling me 2 that valsartan with NDMA is acceptable to be 3 sold with 1,000 ppm. 4 You're not saying that, are 5 you? 6 A. I'm saying -- 7 MR. GALLAGHER: Objection. 8 Mischaracterizes. 9 THE WITNESS: I'm sorry again. 10 I'm saying since the beginning 11 impurity K, which is also a 12 nitrosamine compound, okay, right, the 13 impurity K has been allowed by 14 Novartis as well as by regulatory 15 agencies, okay, at 1,000 ppm since the 16 very beginning. 17 BY MR. SLATER: 18 Q. Didn't we establish a little 19 earlier that you don't know what the FDA 20 decision was with regard to impurity K? 21 A. I told you that -- 22 MR. GALLAGHER: Objection. 23 Outside the scope, asked and answered. 24 A. I told you I don't know what's</p> |

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| <p style="text-align: right;">Page 170</p> <p>1 the current FDA position. But I told you, 2 you know, based upon a European regulatory 3 agency's, you know, a document, right, after, 4 you know, these events, they specifically 5 discussed, you know, impurity K.</p> <p>6 So based upon the knowledge 7 from there, you know, that's how we came to 8 know the impurity K has been, you know, at 9 least, you know, towards that point, being 10 controlled by Novartis at 1,000 ppm.</p> <p>11 BY MR. SLATER:</p> <p>12 Q. Okay. I'm asking about NDMA 13 now. You understand that, right?</p> <p>14 A. If you want to talk, yeah, we 15 can talk now.</p> <p>16 Q. It would never be acceptable to 17 sell valsartan contaminated with NDMA, right? 18 That would never be acceptable, right?</p> <p>19 MR. GALLAGHER: Objection. 20 Vague, outside the scope, and calls 21 for speculation.</p> <p>22 A. You know, I'm not a 23 toxicologist, okay? So if you really want me 24 to answer this question, I may give you my</p> | <p style="text-align: right;">Page 172</p> <p>1 some of the most recent training, FDA's, you 2 know, like training, you know, you know, you 3 know, training slides, it -- you know, you 4 know, it mentioned that, you know, as I said 5 earlier, you know, endogenously formed NDMA 6 could be, you know, anywhere from 1,000 to 7 more than 2,000 microgram per day. So this 8 is, you know, extremely high. I mean...</p> <p>9 So basically, you know, without 10 taking any medication, anyone will have that 11 much of NDMA in you and me and everybody 12 else's body, okay, 1,000 to more than 2,000 13 microgram per day. This is from the official 14 FDA's, you know, you know, training 15 documents.</p> <p>16 So basically our understanding 17 with regard to, you know, you know, the 18 potential toxicity of NDMA, it looks like 19 it's still progressing.</p> <p>20 BY MR. SLATER:</p> <p>21 Q. The FDA is not permitting ZHP 22 to sell valsartan with NDMA impurity in the 23 United States even up until the present day, 24 correct?</p> |
| <p style="text-align: right;">Page 171</p> <p>1 personal, you know, limited understanding by 2 going through, you know, you know, the 3 documents released by FDA particularly, some 4 very recent, you know, training documents by 5 FDA, right?</p> <p>6 So, I mean, for a reliable 7 intake on the specification for NDMA, even 8 from the perspective of FDA, they have 9 changed quite a bit, okay?</p> <p>10 At the very beginning after, 11 you know, you know, these events, FDA's 12 position for NDMA was it should be absent. 13 Okay. So basically, you know, you know, the 14 specification would be defined by the limit 15 of detection of a particular, you know, 16 analytical method.</p> <p>17 But then, you know, after I 18 don't know how long, maybe about a year or 19 so, FDA, you know, then said that, you know, 20 after all of the understanding, you know, of 21 the new knowledge, you know, now they allow, 22 you know, it to be present like 96 nanogram 23 per day, right, for, you know, valsartan. 24 And also if you look through</p> | <p style="text-align: right;">Page 173</p> <p>1 MR. GALLAGHER: Objection. 2 Outside of the scope.</p> <p>3 BY MR. SLATER:</p> <p>4 Q. Correct statement, right?</p> <p>5 A. At this point, you know, the 6 import ban is still there, but there's a lot 7 of reasons. I think partly because of the 8 pandemic.</p> <p>9 We had a meeting with FDA, I 10 think at the end of 2019. During that 11 meeting, you know, FDA has pretty much, you 12 know, accepted our explanation, our 13 responses, and the consensus was they would 14 come over early 2020 to come over on site to 15 do like, you know, a follow-up inspection.</p> <p>16 Q. The fact stands that from the 17 time the FDA learned about NDMA in valsartan, 18 they told ZHP to stop selling it and recall 19 it, right?</p> <p>20 A. The only --</p> <p>21 MR. GALLAGHER: Objection. 22 Outside the scope, and 23 mischaracterizes, lack of foundation.</p> <p>24 Go ahead.</p> |

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| <p style="text-align: right;">Page 174</p> <p>1 THE WITNESS: Yeah, sorry. 2 Yeah. 3 I mean, only after certain 4 period, you know, of the 5 investigation, you know, and then, you 6 know, FDA had the warning letter and 7 also the import ban. 8 And, you know, once we 9 confirmed, you know, the presence of 10 NDMA, you know, in valsartan, we 11 reported it to the FDA, and we give 12 FDA our methods, and also we give FDA 13 our testing results, right, only like 14 maybe like two, three weeks, you know, 15 after June 6th. 16 And we had been talking to FDA, 17 asking for their guidance as to what 18 we should do, right? Whether we 19 should -- to do the recall, you know, 20 immediately or whatever. 21 But, you know, I think, you 22 know, during some of the early 23 response from FDA, you know, FDA still 24 at the time wasn't sure how to -- you</p> | <p style="text-align: right;">Page 176</p> <p>1 To the extent you know, Dr. Li, 2 you can answer. 3 A. Yeah, to the extent -- probably 4 not, to the extent that I know. 5 BY MR. SLATER: 6 Q. Well, speaking for ZHP 7 regarding the root cause investigation, as 8 part of that interaction with the FDA on your 9 root cause investigation, did you tell the 10 FDA that you had knowledge going back to 2017 11 and likely earlier that quenching the 12 valsartan with sodium nitrite was creating 13 NDMA? 14 Did you tell the FDA that? 15 A. As I said -- 16 MR. GALLAGHER: Hang on, 17 Dr. Li. Sorry. Just pause for a 18 minute after the question to give me a 19 chance to object. 20 So objection, outside the 21 scope. 22 The topic number 2 is the root 23 cause investigation for nitrosamine 24 impurities, including NDMA and NDEA in</p> |
| <p style="text-align: right;">Page 175</p> <p>1 know, how to move forward. They 2 specifically asked us to hold on, you 3 know, you know, to any recall, you 4 know, that we would like to do. 5 BY MR. SLATER: 6 Q. You spoke to the FDA, right? 7 A. Yeah, yeah. I was in the 8 meeting with FDA, yeah, at the end of, you 9 know, 2019, yes. 10 Q. Did you tell the FDA that your 11 company knew going back to at least July of 12 2017 and likely earlier, that you knew that 13 NDMA was occurring in valsartan due to the 14 quenching with sodium nitrite? 15 Did you tell that to the FDA? 16 A. I didn't have that knowledge, 17 as I said. Although, you know, it looks like 18 I was on the e-mail. But, as I said, I, you 19 know -- 20 Q. Did anybody tell that to the 21 FDA from your company in 2018 or 2019 or 2020 22 or 2021? 23 MR. GALLAGHER: Objection. 24 Outside the scope.</p> | <p style="text-align: right;">Page 177</p> <p>1 the ZHP API, as we've discussed that, 2 and you have other topics about 3 regulatory issues and discussions with 4 FDA that's not within the topics for 5 today. So outside the scope. 6 Dr. Li, to the extent you know 7 personally, you can answer. 8 MR. SLATER: I'll ask the 9 question again. 10 BY MR. SLATER: 11 Q. As part of ZHP's root cause 12 investigation, did ZHP share with the FDA 13 that ZHP knew going back to at least 14 July 2017 and likely earlier that the 15 quenching of the valsartan with sodium 16 nitrite was the cause of the creation of 17 NDMA? 18 MR. GALLAGHER: Objection. 19 Outside the scope. 20 To the extent you know 21 personally, you can answer, Dr. Li. 22 A. I think I already, you know, 23 answered that question. 24 ///</p> |

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| <p style="text-align: right;">Page 178</p> <p>1 BY MR. SLATER:</p> <p>2 Q. The answer is no, nobody told</p> <p>3 the FDA, right?</p> <p>4 A. As far as I aware.</p> <p>5 MR. SLATER: Cheryll, let's</p> <p>6 take this down and go, if we could --</p> <p>7 see how quick you are -- to</p> <p>8 Exhibit 208, which is the FDA Draft</p> <p>9 Guidance from December 2008.</p> <p>10 MS. CALDERON: It will take me</p> <p>11 a minute.</p> <p>12 MR. SLATER: I thought you were</p> <p>13 going to pull it up and say you read</p> <p>14 my mind.</p> <p>15 Q. Let me ask you this while</p> <p>16 Cheryll is looking for the document.</p> <p>17 MR. SLATER: You can leave this</p> <p>18 e-mail up for a moment, Cheryll.</p> <p>19 Q. Did ZHP ever share this</p> <p>20 July 27, 2017 e-mail with the FDA?</p> <p>21 MR. GALLAGHER: Objection.</p> <p>22 Outside the scope.</p> <p>23 Dr. Li, to the extent you know</p> <p>24 personally, you can answer.</p> | <p style="text-align: right;">Page 180</p> <p>1 speculation.</p> <p>2 BY MR. SLATER:</p> <p>3 Q. You've interacted with the FDA,</p> <p>4 you know the interest they have in this</p> <p>5 nitrosamine impurity issue. Do you think</p> <p>6 they'd like to see the e-mail now?</p> <p>7 MR. GALLAGHER: Objection.</p> <p>8 Still calls for speculation.</p> <p>9 A. I don't know.</p> <p>10 BY MR. SLATER:</p> <p>11 Q. We've put up on the screen</p> <p>12 Exhibit 208, the FDA "Guidance for Industry"</p> <p>13 regarding "Genotoxic and Carcinogenic</p> <p>14 Impurities in Drug Substances and Products,"</p> <p>15 with the "Recommended Approaches."</p> <p>16 And this is FDA guidance.</p> <p>17 You're familiar with this document, aren't</p> <p>18 you?</p> <p>19 A. I read through it before.</p> <p>20 MR. SLATER: And let's go to</p> <p>21 page 8, please, Cheryll, the top</p> <p>22 carryover paragraph, please. You got</p> <p>23 it. I just want the top -- the top of</p> <p>24 the page. Scroll up. Yes. Perfect.</p> |
| <p style="text-align: right;">Page 179</p> <p>1 A. I don't know personally.</p> <p>2 BY MR. SLATER:</p> <p>3 Q. Did you tell the FDA, as part</p> <p>4 of your interactions with them when they were</p> <p>5 trying to learn the root cause of what had</p> <p>6 happened, that you had directed people in</p> <p>7 your department to cease work on a report</p> <p>8 that was being prepared regarding the</p> <p>9 creation of nitroso compounds due to sodium</p> <p>10 nitrite quenching because of the sensitivity</p> <p>11 of the impurity?</p> <p>12 Did you tell that to the FDA?</p> <p>13 MR. GALLAGHER: Objection.</p> <p>14 Outside the scope, mischaracterizes</p> <p>15 testimony and documents.</p> <p>16 A. I didn't ask them to seize --</p> <p>17 you know, to seize the work. The work has</p> <p>18 already been done, right.</p> <p>19 BY MR. SLATER:</p> <p>20 Q. Well, do you think the FDA</p> <p>21 would like to see that e-mail now? Do you</p> <p>22 think they'd be interested in it?</p> <p>23 MR. GALLAGHER: Objection.</p> <p>24 Outside the scope, calls for</p> | <p style="text-align: right;">Page 181</p> <p>1 Q. Looking at the --</p> <p>2 MR. SLATER: Can you scroll up</p> <p>3 more? Because it's confusing,</p> <p>4 actually. No, the other way. Yes.</p> <p>5 All right. Perfect.</p> <p>6 Q. Looking at the carryover</p> <p>7 paragraph on page 8, they're talking about</p> <p>8 the threshold approach. And you've been</p> <p>9 talking about threshold during this</p> <p>10 deposition, correct?</p> <p>11 A. We had some discussion, yeah,</p> <p>12 about the specification, yeah.</p> <p>13 Q. And as of 2008, looking at the</p> <p>14 last sentence in that carryover paragraph on</p> <p>15 page 8, it says, "However, there are some</p> <p>16 compounds containing certain structural</p> <p>17 groups, (aflatoxin-like-, N-nitroso- and</p> <p>18 azoxy-structures) that have extremely high</p> <p>19 carcinogenic potency and are excluded from</p> <p>20 the threshold approach."</p> <p>21 Do you see what I just read?</p> <p>22 A. Mm-hmm.</p> <p>23 Q. In terms of the knowledge of</p> <p>24 the health risks and what's acceptable, your</p> |

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| <p style="text-align: right;">Page 182</p> <p>1 company, ZHP, absolutely knew this after it 2 came out in 2008, right?</p> <p>3 MR. GALLAGHER: Objection. 4 Outside the scope, and lacks 5 foundation.</p> <p>6 A. That was before my joining the 7 company. I had no specific knowledge, but my 8 guess, it should be -- somebody should have 9 read through this document.</p> <p>10 BY MR. SLATER:</p> <p>11 Q. Certainly.</p> <p>12 And in the context of Topic 36, 13 which was ZHP's evaluation and knowledge of 14 the health risks of nitrosamines, this is 15 important information saying that N-nitroso 16 structures "have extremely high carcinogenic 17 potency and are excluded from the threshold 18 approach."</p> <p>19 That's an important piece of 20 information, correct?</p> <p>21 MR. GALLAGHER: Objection. 22 Vague.</p> <p>23 A. That's what it state in this 24 document. Okay.</p> | <p style="text-align: right;">Page 184</p> <p>1 allow that to be in these drug substances, 2 correct? 3 That's the decision that's been 4 made around the world, correct?</p> <p>5 MR. GALLAGHER: Objection. 6 Outside the scope, calls for 7 speculation, and calls for expert 8 testimony.</p> <p>9 A. As I said, you know, based upon 10 some recently released material, training 11 material by FDA, I think, you know, the 12 potential risk -- our knowledge of the 13 potential risk is still evolving, okay.</p> <p>14 And also, as I said, some of 15 the N-nitroso compounds, they are not 16 genotoxic, okay, like impurity K.</p> <p>17 But anything else, you know, I 18 think it will up to, you know, a professional 19 toxicologist, you know, to do further 20 evaluation.</p> <p>21 BY MR. SLATER:</p> <p>22 Q. In terms of ZHP's evaluation 23 and knowledge of the health risks of 24 nitrosamines, you would certainly agree with</p> |
| <p style="text-align: right;">Page 183</p> <p>1 But also, you know, I think in 2 this document, or maybe in a more updated, 3 you know, M7, it also said, you know, you 4 know, these approach usually are very 5 conservative.</p> <p>6 BY MR. SLATER:</p> <p>7 Q. Well, M7 says that "Some 8 structural groups were identified to be of 9 such high potency that intakes even below the 10 threshold of toxicological concern would 11 theoretically be associated with a potential 12 for a significant carcinogenic risk. This 13 group of high potency mutagenic carcinogens," 14 referred to as the "cohort of concern," 15 "comprises aflatoxin-like-, N-nitroso-, and 16 azoxy compounds."</p> <p>17 You know that's what M7 says, 18 right?</p> <p>19 A. Yes. But also it said 20 potential, yeah.</p> <p>21 Q. The point is this. The 22 regulators around the world have determined 23 that with the N-nitroso compounds, the risk 24 of causing cancer to humans is too high to</p> | <p style="text-align: right;">Page 185</p> <p>1 me that with regard to NDMA and NDEA, the 2 nitrosamines at issue in this litigation, 3 they're considered to be high potency 4 mutagenic carcinogens, correct?</p> <p>5 A. They're considered to be -- 6 well, those are the data based upon animal 7 studies, okay. They are considered as 8 potential or probable carcinogenic to humans, 9 so this has not been fully confirmed.</p> <p>10 Q. Based on the studies that have 11 been performed, they're considered to be 12 probable high potency mutagenic carcinogens. 13 That's the considered wisdom at present, 14 correct?</p> <p>15 MR. GALLAGHER: Objection. 16 Vague.</p> <p>17 A. As I said, you know, the common 18 consensus based upon FDA's release document 19 or European, you know, regulators, yeah, NDMA 20 or NDEA, they are potential or probable, you 21 know, carcinogen to human.</p> <p>22 BY MR. SLATER:</p> <p>23 Q. The word is "probable." 24 They're considered probable, correct?</p> |

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| <p style="text-align: right;">Page 186</p> <p>1 A. Probable, you know, which means 2 it's not confirmed. It's not fully 3 confirmed.</p> <p>4 Q. You're a scientist. "Probable" 5 means more likely than not, right?</p> <p>6 A. Probably is probable, whatever 7 that -- you know, yeah, we can look at the 8 dictionary, yeah, probable, yeah.</p> <p>9 But, again, probable, you know, 10 you know, again, is not a sure thing. I 11 mean, probable, you know, a lot of things 12 could be probable but eventually didn't 13 happen.</p> <p>14 Q. You mentioned the word -- 15 rephrase.</p> <p>16 You used the word a moment ago 17 "consensus." The consensus among those 18 people who are responsible for this issue is 19 NDMA and NDEA are probable human carcinogens, 20 and they shouldn't be in drug substances for 21 that reason, because it's considered to be 22 too high a risk for humans, correct?</p> <p>23 MR. GALLAGHER: Objection.</p> <p>24 Vague --</p> | <p style="text-align: right;">Page 188</p> <p>1 valsartan far exceeded that level, correct?</p> <p>2 A. Based upon the current 3 knowledge, yes.</p> <p>4 Q. The levels of NDMA in ZHP's 5 valsartan are considered to be unacceptable 6 for human consumption, right?</p> <p>7 MR. GALLAGHER: Objection.</p> <p>8 Vague.</p> <p>9 A. That's retrospective. That's 10 based upon today's knowledge, okay. This may 11 change over time, you know, either be 12 tightened or even maybe be loosened, okay, 13 because the reason, again, you know, based 14 upon FDA release the training document, you 15 know, they endogenously formed NDMA, right?</p> <p>16 As I said, you know, anybody 17 like you and me, you know, just by, you know, 18 changing the normal food, the NDMA then will 19 be formed because of just simply by taking 20 the food, it will be produced anywhere 21 between 1,000 microgram to 2,000 -- you know, 22 more than 2,000 microgram per day.</p> <p>23 Q. What are you quoting for those 24 numbers?</p> |
| <p style="text-align: right;">Page 187</p> <p>1 BY MR. SLATER:</p> <p>2 Q. That's the consensus, right?</p> <p>3 MR. GALLAGHER: Objection.</p> <p>4 Vague, calls for speculation, and 5 expert testimony.</p> <p>6 A. Your question is not accurate.</p> <p>7 You know, and I think I answered that 8 question before, okay?</p> <p>9 You know, based upon, you know, 10 the current, you know, consensus, at least 11 from FDA, okay, you know, based upon your 12 process, I mean, obviously the best way would 13 be to avoid. But we know, you know, for 14 the -- you know, for the -- you know, for the 15 valsartan, you know, you know, process 16 chemistry, it looks like, you know, you just 17 cannot avoid, you know, the formation.</p> <p>18 So it's a certain level of NDMA 19 would be allowed, okay. So, as I said, right 20 now the consensus is 96 nanogram per day, 21 okay. That's considered to be lifetime, you 22 know, you know, allowable intake level.</p> <p>23 BY MR. SLATER:</p> <p>24 Q. The levels of NDMA in ZHP's</p> | <p style="text-align: right;">Page 189</p> <p>1 A. Those are from the recent FDA 2 trainings, you know, you know, document. I 3 think, you know, my counsel can send these 4 documents to you. I mean, these are, you 5 know, publicly available information.</p> <p>6 Q. Are you telling us that because 7 certain nitrosamines can form at very low 8 levels in nature, that it's acceptable that 9 ZHP was selling valsartan --</p> <p>10 (Over-speaking.)</p> <p>11 A. No, no, no. Don't twist.</p> <p>12 Q. Are you saying that or not?</p> <p>13 A. No, I'm not saying that. I'm 14 just saying the fact, okay? I'm not 15 saying -- okay. What I'm telling you is 16 several facts, okay, right?</p> <p>17 First of all, you know, 18 FDA's -- after the events, right, FDA's -- 19 first of all, you know, at the time, you 20 know, nobody knew, you know, you know, 21 immediately what the -- you know, a limit or 22 an interim limit should be, right?</p> <p>23 And then so after some time, 24 you know, the interim limit was established,</p> |

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| <p style="text-align: right;">Page 190</p> <p>1 okay? The interim limits was 96 nanogram per 2 day, okay.</p> <p>3 And then, you know, after some 4 time FDA's position was that NDMA, also NDEA, 5 should be absent, right?</p> <p>6 And then more recently, you 7 know, they loosened the standard, okay, 8 they -- you know, the NDMA now, you know, 9 being allowed, you know, to a maximum level 10 96 nanogram per day, right?</p> <p>11 So -- but in the training, 12 FDA's training material, you know, you know, 13 they had those things, you know, they had, 14 you know, those discussions.</p> <p>15 So, yeah, so based upon that, 16 you know, you know, you know, you know, the 17 material -- okay, also based upon the 18 principle of M7, right?</p> <p>19 And that's a reasonable 20 speculation that, you know, FDA or 21 somebody -- you know, other regulator they 22 may, you know, change the acceptable limits 23 in the future, okay?</p> <p>24 You know, because if you look</p> | <p style="text-align: right;">Page 192</p> <p>1 know, that would be the case. But don't 2 forget, you know, we have the -- you know, we 3 didn't have that specification. And all the, 4 you know, all the specification that we 5 tested, you know, and released upon, they 6 have been submitted and also approved by 7 regulatory agencies, including FDA.</p> <p>8 BY MR. SLATER:</p> <p>9 Q. Well, you're certainly not 10 telling me that ZHP and yourself, who joined 11 the company in 2014, could have thought that 12 the levels of NDMA in your valsartan would 13 have been acceptable back in 2014 or 2015 or 14 2016 or 2017 or 2018?</p> <p>15 You're not telling me that ZHP 16 would have thought these levels would have 17 been acceptable, are you?</p> <p>18 MR. GALLAGHER: Objection.</p> <p>19 A. As I said --</p> <p>20 MR. GALLAGHER: Wait, hang on.</p> <p>21 Objection. Vague, compound, 22 calls for speculation, expert 23 testimony, and asked and answered.</p> <p>24 ///</p> |
| <p style="text-align: right;">Page 191</p> <p>1 at the -- you know, the M7, right, it says if 2 data, you know, potential genotox impurity, 3 if they -- you know, if they come, you know, 4 if the source for another source, right, 5 other than a medication is more than, you 6 know, what you can take from a medical 7 product, you know, then -- you know, then in 8 general, you know, you know, their level, you 9 know, may be -- you know, may be loosened, 10 okay, based upon, you know, that fact.</p> <p>11 Q. The levels of NDMA in ZHP's 12 valsartan would never have been acceptable in 13 2014, 2015, 2016, 2017, or 2018?</p> <p>14 MR. GALLAGHER: Objection.</p> <p>15 Vague, compound.</p> <p>16 BY MR. SLATER:</p> <p>17 Q. Do you agree with me those 18 levels were so high, they never would have 19 been acceptable in any of those years, 20 correct?</p> <p>21 MR. GALLAGHER: Objection.</p> <p>22 Vague, compound, calls for 23 speculation, and expert testimony.</p> <p>24 A. You know, retrospectively, you</p> | <p style="text-align: right;">Page 193</p> <p>1 BY MR. SLATER:</p> <p>2 Q. At that time, you didn't need 3 to say it's retrospective. In 2015, for 4 example, I'm looking at the levels on the 5 documents submitted to the FDA. You had 6 levels of over 100 parts per million in some 7 batches.</p> <p>8 You could never have thought 9 that was acceptable to sell under any 10 circumstances at that time, right?</p> <p>11 MR. GALLAGHER: Objection.</p> <p>12 Vague, calls for expert testimony, 13 argumentative, and lacks foundation.</p> <p>14 A. Again, with a specific level, 15 you know, this is outside of my expertise. 16 As I said, this up to toxicologists, also 17 regulators, you know, finally, you know, you 18 know, their job to determine.</p> <p>19 BY MR. SLATER:</p> <p>20 Q. Validation batch number 1, 21 batch number C5355-12-003 manufactured on 22 December 28, 2011 was tested by your company 23 at NDMA level of 76 parts per million.</p> <p>24 That level, your company never</p> |

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| <p style="text-align: right;">Page 194</p> <p>1 would have thought was acceptable for sale at 2 any point during the entire time valsartan 3 was sold, correct?</p> <p>4 MR. GALLAGHER: Objection. 5 Outside the scope, vague, calls for 6 speculation, and expert testimony.</p> <p>7 THE WITNESS: I don't know, do 8 I need to answer the question?</p> <p>9 MR. GALLAGHER: Yes. To the 10 extent you know, you should answer.</p> <p>11 A. I mean, basically, as I said, 12 you know, retrospectively, you know, you 13 know, those levels are above the current, 14 okay, established limit.</p> <p>15 BY MR. SLATER:</p> <p>16 Q. Those levels were so high that 17 if your company had actually acknowledged to 18 the outside world that NDMA was forming due 19 to the sodium nitrite quenching, you know, 20 and you can agree with me right now, your 21 sale of valsartan would have been shut down 22 immediately as soon as your company disclosed 23 that, correct?</p> <p>24 MR. GALLAGHER: Objection.</p> | <p style="text-align: right;">Page 196</p> <p>1 MR. GALLAGHER: Okay.</p> <p>2 BY MR. SLATER:</p> <p>3 Q. The FDA never indicated that 4 the NDMA levels in the valsartan sold by your 5 company were acceptable. All they said is 6 they had to figure out how much supply was 7 out there due to the extent of the 8 contamination of your pills, and they had to 9 just make sure that there was enough 10 medication out there for people's blood 11 pressure to be controlled for a short period 12 of time.</p> <p>13 That's all the FDA let you do, 14 right?</p> <p>15 MR. GALLAGHER: Objection. 16 Outside the scope, and lacks 17 foundation.</p> <p>18 A. I don't know, you know, because 19 I'm not the person, you know, to be directly 20 involved with the -- you know, with the 21 recall.</p> <p>22 So I don't -- you know, I don't 23 know exactly, you know, what you, you know, 24 just said to me, okay, but, you know,</p> |
| <p style="text-align: right;">Page 195</p> <p>1 Argumentative, calls for speculation, 2 and expert testimony.</p> <p>3 A. That's not the case, okay. As 4 I told you, once we -- you know, after -- you 5 know, after that particular event, after we 6 have got, you know, those data, right, from 7 the initial, like, 50 batches or so, we 8 reported, you know, like up to two, three 9 weeks roughly, we reported it to the FDA. 10 We asked them their guidance, 11 okay, and we mentioned, I think, you know, at 12 least in one of the communications whether we 13 should do the recall. And they specifically 14 told us to be hold on.</p> <p>15 So this is not what you're 16 saying, you know, you know, all right?</p> <p>17 So, essentially, it need to be 18 evaluated by, you know, experts.</p> <p>19 MR. GALLAGHER: Adam, we've 20 been going almost an hour and 21 20 minutes.</p> <p>22 MR. SLATER: I just have a 23 couple quick follow-up questions, and 24 then we can take a break.</p> | <p style="text-align: right;">Page 197</p> <p>1 assuming that's true, so at least, you know, 2 what that indicate, you know, there is no, 3 you know, immediate, you know, you know -- I 4 mean, it still be tolerable considered, you 5 know, that particular medical need.</p> <p>6 And again, you know, you know, 7 the level, like you said, 70-some ppm, is 8 not, you know -- you have saying, you know, 9 you know, you know, consider, for example, 10 like ranitidine, right?</p> <p>11 If you look at ranitidine, 12 okay, this is a compound or is a medication 13 developed by, you know, GSK or its precursor, 14 you know, company, like SmithKline, like 15 about 40 years ago, okay?</p> <p>16 And now we know that, you know, 17 you know, the level, you know, you know, of 18 this, you know, probably -- I think the 19 actual level was like 47 micrograms or 20 something.</p> <p>21 So, yes, so that's, you know, 22 higher than I think our, you know, you know, 23 NDMA, you know, in those batches.</p> <p>24 MR. SLATER: I think that we</p> |

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| <p>1 can take a break off of the ranitidine 2 testimony and take a break, so we can 3 go off the record.</p> <p>4 THE VIDEOGRAPHER: The time 5 right now is 11:01 a.m. We're now off 6 the record.</p> <p>7 (Whereupon, a recess was 8 taken.)</p> <p>9 THE VIDEOGRAPHER: The time 10 right now is 11:16 a.m. We're back on 11 the record.</p> <p>12 BY MR. SLATER:</p> <p>13 Q. We're looking at Exhibit 284, 14 and this is an e-mail sent by some people at 15 Novartis to ZHP on May 22, 2018. 16 Do you see that?</p> <p>17 A. Yeah, it looks like, yeah. 18 Mm-hmm.</p> <p>19 Q. And the e-mail says, "Dear 20 Huahai colleagues, During our analysis of 21 residual solvents by GC (using a combined 22 method) at Novartis we have found a number of 23 solvents that we cannot identify for the 24 following batches. The peak areas vary</p> | <p>Page 198</p> <p>1 And this is June 5, 2008 -- 2 rephrase.</p> <p>3 Looking now at Exhibit 288, 4 this is a June 5, 2018 e-mail, again from 5 Novartis to multiple people in your company, 6 including yourself, correct?</p> <p>7 A. Let me see whether -- am I on 8 it? Let me --</p> <p>9 Q. Second-to-last line of the CC 10 list.</p> <p>11 A. Oh, yes, mm-hmm. Yeah.</p> <p>12 Q. You're there, and just above 13 you is Peng Dong. 14 Do you see that?</p> <p>15 A. Yes, mm-hmm. I saw him, yes.</p> <p>16 Q. Two of the people who received 17 that July 2017 e-mail we've gone through from 18 Jinsheng Lin, correct?</p> <p>19 A. Yes, mm-hmm.</p> <p>20 Q. And at this point now Novartis 21 advises you that "We have done some tests in 22 Solvias labs for Novartis of three batches of 23 Huahai material and have a tentative 24 assessment."</p> |
| <p>1 depending on the batch. These are the 2 batches analyzed."</p> <p>3 And they give the list of the 4 batches, right?</p> <p>5 A. It looks like, mm-hmm.</p> <p>6 Q. And ultimately they also attach 7 their gas chromatography method for ZHP to 8 review and ask, "I would appreciate your 9 support on this and feel free to call me if 10 any further information is required."</p> <p>11 So they were asking ZHP, what 12 are these unknown peaks in these various 13 batches of valsartan API, correct?</p> <p>14 A. Yes, mm-hmm.</p> <p>15 Q. And we know in retrospect, as 16 you've said earlier, that gas 17 chromatography-mass spectrometry, if focused 18 at that time, would show NDMA, correct?</p> <p>19 MR. GALLAGHER: Objection.</p> <p>20 Mischaracterizes testimony.</p> <p>21 A. No, I didn't.</p> <p>22 BY MR. SLATER:</p> <p>23 Q. Well, let's go further then.</p> <p>24 Let's go now to Exhibit 288.</p> | <p>Page 199</p> <p>1 And they then point out that 2 they're asking for your company to assess 3 this and comment as soon as possible, right?</p> <p>4 A. Yeah, looks like, mm-hmm.</p> <p>5 MR. SLATER: And as we flip 6 through, Cheryll, if could you go 7 forward to the page that says 798, 8 with regard to the first batch that 9 was tested.</p> <p>10 Q. Do you see there that there's 11 identification of NDMA, and it says 12 "tentative," correct?</p> <p>13 A. Yes.</p> <p>14 Q. And you're familiar with this 15 document, right? So you know that for the 16 next two batches, the same finding was made, 17 right?</p> <p>18 A. Mm-hmm.</p> <p>19 Q. And the NDMA in the valsartan 20 is what was discussed by Jinsheng Ling in the 21 July 2017 e-mail, correct?</p> <p>22 A. He was not specifically at the 23 time talking about this particular peak. He 24 just -- at that time he was making, you know,</p> |

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| <p>1 you know, a guess.</p> <p>2 Q. He was -- well, he -- rephrase.</p> <p>3 He said that NDMA occurs in</p> <p>4 valsartan when quenched with sodium nitrite,</p> <p>5 and this here in June of 2018 is Novartis</p> <p>6 bringing to your attention that they</p> <p>7 tentatively think they've identified a peak</p> <p>8 that shows NDMA in valsartan, correct?</p> <p>9 A. Yes.</p> <p>10 Q. At any point in the</p> <p>11 communications with Novartis, did you or</p> <p>12 anybody else from ZHP tell Novartis that your</p> <p>13 company knew at least as of July 2017 that</p> <p>14 NDMA was forming in the valsartan that was</p> <p>15 quenched with sodium nitrite?</p> <p>16 Did you tell Novartis about</p> <p>17 that?</p> <p>18 A. I don't remember what we</p> <p>19 responded. I mean, can you go down to the --</p> <p>20 or go through the whole e-mail?</p> <p>21 Q. Well, this is the e-mail.</p> <p>22 There's no response to it. That's the</p> <p>23 e-mail. You're seeing at the top of the</p> <p>24 first page --</p> | <p>Page 202</p> <p>1 shows that that was disclosed, right?</p> <p>2 A. Not as far as I know.</p> <p>3 Q. Let's now go to Exhibit 289,</p> <p>4 which is the report from Solvias that was</p> <p>5 provided with the June 5, 2018, e-mail.</p> <p>6 You've seen this report,</p> <p>7 correct?</p> <p>8 A. Yes.</p> <p>9 MR. SLATER: And let's go now</p> <p>10 to the second page of this document</p> <p>11 where the objective is listed.</p> <p>12 Perfect.</p> <p>13 Q. And the objective of this study</p> <p>14 was as follows. "Unknown compounds were</p> <p>15 detected in the analysis of residue solvents</p> <p>16 in Valsartan, a product of Novartis</p> <p>17 International Pharmaceuticals." I'll stop</p> <p>18 there.</p> <p>19 And the reason it says that is</p> <p>20 because, as you know, Novartis had purchased</p> <p>21 this API from ZHP and then provided it to</p> <p>22 Solvias to test it, correct?</p> <p>23 A. Yes.</p> <p>24 Q. And then this says, "Solvias</p> |
| <p>Page 203</p> <p>1 MR. SLATER: Cherryl, you can</p> <p>2 go back to the beginning.</p> <p>3 Q. -- that is the e-mail.</p> <p>4 A. That's the whole?</p> <p>5 Q. So my question is this.</p> <p>6 Did ZHP tell Novartis that ZHP</p> <p>7 knew at least as of July 2017 that there was</p> <p>8 NDMA in its valsartan? I just want to know</p> <p>9 if your company told that to Novartis.</p> <p>10 A. I don't remember. I don't</p> <p>11 know. I mean, I -- you know, I was not</p> <p>12 involved, you know, in most of those, you</p> <p>13 know, you know, e-mail communication. I</p> <p>14 was -- some of those e-mail communication,</p> <p>15 just telling them about some technical</p> <p>16 issues, I think.</p> <p>17 Q. Well -- rephrase.</p> <p>18 Have you seen anything</p> <p>19 indicating that ZHP disclosed to Novartis</p> <p>20 when Novartis came with its concerns about</p> <p>21 these unknown peaks that your company already</p> <p>22 knew that there was NDMA in the valsartan?</p> <p>23 A. I have no knowledge.</p> <p>24 Q. You haven't seen anything that</p> | <p>Page 205</p> <p>1 received the task from Novartis to analyse</p> <p>2 and identify the unknown compounds using</p> <p>3 Headspace GC/MS analysis."</p> <p>4 And I want to stop there and</p> <p>5 ask you, "GC/MS analysis" is gas</p> <p>6 chromatography-mass spectrometry, correct?</p> <p>7 A. Yes.</p> <p>8 Q. That's a technology that's been</p> <p>9 available -- as of 2018, for how long had</p> <p>10 that been available?</p> <p>11 A. It was quite long.</p> <p>12 Q. And then it says, "This report</p> <p>13 summarizes the results of this analysis."</p> <p>14 Correct?</p> <p>15 A. Mm-hmm.</p> <p>16 Q. And by the way, when you say</p> <p>17 that GC-MS was available for quite a long</p> <p>18 time, it certainly was available as of 2011</p> <p>19 when these processes were being developed by</p> <p>20 ZHP, correct?</p> <p>21 A. It was available as an</p> <p>22 instrument, you know, to the market.</p> <p>23 I just -- you know, you know,</p> <p>24 yesterday I just asked, you know, you know,</p> |

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| <p style="text-align: right;">Page 206</p> <p>1 Mr., you know, Chen, you know, Wenbin Chen, 2 you know, also on one of the e-mails, I ask 3 him when we receive the first one. 4 I think it was somewhere like 5 in 2013, Huahai, or at least, you know, you 6 know, that organization prior to my joining, 7 you know, that technical, you know, 8 supporting group, you know, was getting the 9 first one somewhere in 2013, yes.</p> <p>10 Q. When you're testifying right 11 now, are you testifying that you know that 12 ZHP got its first GC-MS machine in 2013?</p> <p>13 A. Yes.</p> <p>14 Q. Are you sure they didn't have 15 one earlier?</p> <p>16 A. Well, at least not in my 17 organization, on my prior, you know, 18 organization that I inherited.</p> <p>19 Yeah, they may have -- I don't 20 know. I mean, like, you know, in the 21 headquarters, you know, organizations, you 22 know, like in Xunqiao, right, yeah, that was 23 the first GC-MS that was there.</p> <p>24 Q. One of the things that a</p> | <p style="text-align: right;">Page 208</p> <p>1 withdraw the outside the scope 2 objection. 3 But it's vague, lacks 4 foundation, and calls for speculation 5 and expert testimony.</p> <p>6 BY MR. SLATER:</p> <p>7 Q. You know that, right, that it's 8 been known for many years, going back at 9 least to the 1970s, that GC-MS is the best 10 method to identify nitrosamines, correct?</p> <p>11 MR. GALLAGHER: Same 12 objections.</p> <p>13 A. I only know retrospectively 14 people have done, you know, previously, but 15 not, you know, with valsartan or any other 16 sartans.</p> <p>17 And, you know, when you 18 mentioned 1970s, I don't remember, you know, 19 you know, the specific time frame.</p> <p>20 But again, GC-MS has been 21 mostly, you know, more like a research tool 22 for QC residual solvent method. GC-FID 23 method remains to be, even as of today, you 24 know, the choice of, you know, of the method</p> |
| <p style="text-align: right;">Page 207</p> <p>1 company like ZHP should do is make sure that 2 it obtains the type of technology that's 3 available for it to manufacture quality 4 substances, correct?</p> <p>5 MR. GALLAGHER: Objection.</p> <p>6 Vague, and outside the scope.</p> <p>7 A. You know, the residual solvent 8 method typically uses GC-FID technology, 9 okay? So for those, you know -- so typically 10 people will not do the GC-MS, you know, to 11 develop a residual solvent method.</p> <p>12 BY MR. SLATER:</p> <p>13 Q. It's been known since the 1970s 14 and going back that GC-MS is the best way to 15 identify nitrosamines, correct?</p> <p>16 MR. GALLAGHER: Objection.</p> <p>17 Vague, lacks foundation, calls for 18 speculation and expert testimony, and 19 outside the scope.</p> <p>20 MR. SLATER: It's outside the 21 scope of the chromatogram and mass 22 spectrometry with --</p> <p>23 (Over-speaking.)</p> <p>24 MR. GALLAGHER: I would</p> | <p style="text-align: right;">Page 209</p> <p>1 for controlling residual solvents.</p> <p>2 MR. SLATER: Well, let's now go 3 to page -- the Bates number is 13 in 4 the bottom right. Keep going. Let's 5 get the whole bottom half of the page 6 in. Perfect. Thank you, Cheryll.</p> <p>7 BY MR. SLATER:</p> <p>8 Q. Looking now at Figure 2 in the 9 Solvias report, it's a chromatogram of 10 valsartan, and it has the batch number 11 18-038M01, provided by Novartis to Solvias.</p> <p>12 Do you see that?</p> <p>13 A. Mm-hmm.</p> <p>14 Q. Can you tell what type of 15 chromatogram that is?</p> <p>16 A. Yeah, it looks like a 17 chromatogram from GC-MS analysis.</p> <p>18 Q. And if you look at it, it says 19 that Table 4 -- rephrase.</p> <p>20 First of all, looking at the 21 chromatogram itself -- actually, we'll come 22 back to that. Looking at -- rephrase.</p> <p>23 Below the Figure 2, the 24 chromatogram, it says in part, "Table 4</p> |

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| <p style="text-align: right;">Page 210</p> <p>1 displays the corresponding retention times 2 and calculated relative retention times." 3 Do you see that? 4 A. Mm-hmm. Okay. 5 MR. SLATER: And if we scroll 6 to the next page, and then we'll 7 scroll back in a moment, but if we 8 scroll to the next page -- perfect. 9 Q. You see at number 18 toluene 10 with a retention time of 10.46. 11 Do you see that? 12 A. Mm-hmm. 13 Q. And then right below it, number 14 19, it says "not applicable, 12.25." 15 Do you see that? 16 A. Mm-hmm. 17 Q. And the "not applicable" there 18 means it hasn't been identified, right? 19 A. Probably. 20 Q. And then if you scroll further 21 down into the next table, 5, it says 22 "Tentative identification of unknown peaks 23 detected in Valsartan." 24 MR. SLATER: Cheryll, if you</p> | <p style="text-align: right;">Page 212</p> <p>1 MR. SLATER: If you scroll down 2 a little further down, Cheryll. 3 Perfect. And scroll to the right so 4 we can see the peak to the right. 5 Q. That next peak to the right of 6 the toluene is 12.25. 7 Do you see that? 8 A. Yes, mm-hmm. Okay. 9 Q. And to -- rephrase. 10 And using your terminology, in 11 retrospect and as proven -- well, rephrase. 12 As proven here and as you 13 subsequently confirmed, that's the NDMA peak, 14 correct? 15 A. I don't know, you know -- wait 16 a second. I think on the table, you know, 17 you know, it was their method. This is not 18 NDMA. I think, you know, if I remember 19 correctly just moments ago, the other way 20 should be like, what, 15 something, or what? 21 Can you go down the list? 22 Q. Sure. And you can tell me 23 which one is the NDMA peak. Why don't we do 24 that.</p> |
| <p style="text-align: right;">Page 211</p> <p>1 scroll further, please. 2 Q. 18 and 19 matching up again, at 3 18 we have toluene, correct? 4 A. Mm-hmm. 5 Q. And 19, NDMA, and they call it 6 "tentative," right? 7 A. Right. 8 Q. So based on this, if we go back 9 now to the chromatogram at Figure 2, the 10 toluene is that peak on the right, the taller 11 peak third from the right. And I know that 12 the writing is incredibly small. We can 13 probably blow it up quite a bit. 14 MR. SLATER: So let's do that. 15 A. Sure. 16 Q. I don't know if we can blow it 17 up enough, but I can tell you -- 18 A. Okay. 19 Q. -- that says toluene, 10.46. 20 A. Okay. All right. Okay. This 21 one. Okay. 22 MR. SLATER: Good job, Cheryll. 23 Q. And then the NDMA peak that 24 they identified at 12.25 --</p> | <p style="text-align: right;">Page 213</p> <p>1 A. Well, you know, I'm not very 2 familiar with Novartis', you know -- you 3 know, all of those details, okay. Yeah, 4 going down the other -- yeah. 5 MR. SLATER: Go to the next 6 table, Cheryll. 7 A. Yeah, yeah, yeah, yeah, yeah. 8 Because I don't think -- yeah, it shows the 9 retention time like 15 something. 19. 10 Yeah, 15 -- yeah, see that, 11 yeah, 15 point -- almost 16 minutes. So it 12 should not be that one immediately after, you 13 know, the toluene with their method. 14 Q. Well, in fact, if you look at 15 the retention times for the two different 16 tables, they're actually different, and the 17 one that matches up to the chromatogram is 18 the 10.46 and the 12.25. 19 Do you know why those numbers 20 are different? 21 A. I don't know. I mean, it's 22 their method. 23 THE WITNESS: Can we go up, 24 yeah, and take a look at toluene in</p> |

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| <p>1 the first table? Yeah. I mean, this 2 one -- yeah. 3 A. See where the toluene -- yeah, 4 on the first table -- what's the retention 5 time? 6 Oh, hold on. I'm sorry. Okay. 7 Okay. So -- okay. So, yeah, somehow, you 8 know, the retention time, they're quite 9 different. On this table toluene is like 10 10.46, yeah.</p> <p>11 MR. SLATER: Let me see if we 12 can -- go to the chromatogram, please, 13 Cheryll. Just let's go to the 14 picture.</p> <p>15 Q. Maybe we can find a common 16 ground. What we do know is this. The 17 toluene elutes, and then the NDMA elutes to 18 the right of it, correct?</p> <p>19 A. No. Actually, if you're 20 talking about, you know, ZHP's method, okay, 21 what I can tell you the profile.</p> <p>22 Okay. Yeah. So we have the 23 toluene and then we have the next, like, 24 somewhat, you know, more obvious peak, like</p> | <p>Page 214</p> <p>1 Q. And let me -- explain -- tell 2 me if I understand this correctly. If you do 3 an appropriate risk assessment and know that 4 NDMA potentially formed, and you used GC-MS 5 and looked for NDMA, you can find it, right? 6 MR. GALLAGHER: Objection. 7 Vague and compound, and calls for 8 speculation. 9 A. I mean, retrospectively, if you 10 want to specifically look for it using GC-MS 11 or, you know, GC-MS/MS, yeah, you might be 12 able to find it, yes. 13 BY MR. SLATER: 14 Q. And that's ultimately what 15 happened, right? When ZHP was looking for it 16 after Novartis came to you, you identified 17 it, right? 18 A. Yes. 19 Q. And in fact, as we've talked 20 about earlier in the deposition, we've now 21 seen an e-mail showing that it was discussed 22 within your company almost a year earlier, 23 that your company already knew that NDMA was 24 in the valsartan, correct?</p> |
| <p>Page 215</p> <p>1 the one, you know, you just trying to point 2 out to me like 12 point something, right? 3 But I'm not saying our method, you know, they 4 have this retention time, okay. I'm just 5 talking about, you know, you know, the 6 elution profile, okay? 7 So after the first somewhat 8 more obvious peak, after the toluene, based 9 upon our, you know, analysis, it's not NDMA, 10 okay? That, you know, that peak was n-butyl 11 acetate, okay? And so based upon our 12 analysis retrospectively, the NDMA eluting at 13 the shoulder peak of the n-butyl acetate.</p> <p>14 Q. Okay. So -- rephrase. 15 So the NDMA is to the right of 16 the toluene, correct? 17 A. It's right to the toluene, and 18 also it's right to the first -- you know, 19 yeah, right to the n-butyl acetate. 20 Q. And on this test Solvias was 21 able to tentatively identify the NDMA peak, 22 correct? 23 A. Based upon, yeah, their report, 24 yes.</p> | <p>Page 217</p> <p>1 A. It's not, you know, ZHP knew. 2 I mean, it was Mr. Lin, you know, he made 3 that speculation. 4 Q. He shared that information with 5 you, Peng Dong, Linda Lin, Jucai Ge, people 6 who had important positions in ZHP, right? 7 MR. GALLAGHER: Objection. 8 Vague. 9 A. People who are employed by ZHP 10 at the time, yes. 11 BY MR. SLATER: 12 Q. In important positions, in 13 high-level positions, correct? 14 MR. GALLAGHER: Objection. 15 Vague. 16 A. For some of them, I'm not sure. 17 You know, it could be defined as high-level. 18 For myself, yes, I'm at a high-level 19 position, but not necessarily for every 20 single one of them. 21 BY MR. SLATER: 22 Q. Peng Dong had a -- what about 23 Peng Dong? What position was he in? 24 A. He was -- probably at the time</p> |

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| <p style="text-align: right;">Page 218</p> <p>1 was a technical manager, so I would say this 2 is a middle-level. 3 Q. How about Jucai Ge? 4 A. She was the QA. You know, 5 she's a QA person, yeah. She's responsible, 6 you know, for the QA department. 7 Q. The QA is the quality assurance 8 department, right? 9 A. Right. 10 Q. What does the quality assurance 11 department do? 12 A. They want to ensure, you know, 13 product being manufactured according to, you 14 know, predefined or particularly, you know, 15 file the registrations for the regulatory 16 authorities. 17 Q. And Linda Lin was in the 18 regulatory affairs department, correct? 19 A. Yes. 20 Q. She had a significant position, 21 right? 22 A. She's the head of the 23 regulatory affairs. 24 Q. And all of those people were</p> | <p style="text-align: right;">Page 220</p> <p>1 irbesartan, not -- you know, that 2 particular irbesartan, you know, 3 N-nitroso compound of the irbesartan, 4 so it's not, you know, NDMA. 5 BY MR. SLATER: 6 Q. Well, you knew in April 2018 7 that you didn't want that report that your 8 department was working on to be completed or 9 shown to anybody, and that's why you said -- 10 A. No. No, it's -- 11 Q. -- not to go further with that 12 report, right? 13 A. Well, see, I mean, you know, 14 the -- you know, as I said, the work has 15 already been -- you know, been done. 16 You know, the reason, as I have 17 explained, you know, I don't want to create a 18 confusion, you know what I'm saying? And, 19 you know, you know, was mixed up with, you 20 know, those things. 21 You know, because, you know, 22 the topic of that document, you know, was 23 about, you know, an impurity. That impurity 24 was not even, you know, you know, you know,</p> |
| <p style="text-align: right;">Page 219</p> <p>1 put on notice at least as of July 2017 that 2 there was NDMA in the valsartan, right? 3 A. I mean, based upon that e-mail, 4 I mean, you know, Mr. Lin made that e-mail. 5 But again, you know, it looks like -- you 6 know, it's just people maybe didn't go 7 through or people maybe just saw that he's 8 making, you know, exaggerations or... 9 Q. But in reality he was right, 10 and that's been proven, correct? 11 MR. GALLAGHER: Objection. 12 Asked and answered, and 13 mischaracterizes the testimony. 14 A. As I -- 15 I mean, do I need to answer? 16 MR. GALLAGHER: You can answer. 17 THE WITNESS: Okay. 18 I mean, as I, you know, 19 answered earlier, I mean, basically, 20 you know -- you know, at that time, 21 you know, you know, as I said, he was 22 making his guess. 23 But also, you know, the topic 24 of the e-mail was talking about</p> | <p style="text-align: right;">Page 221</p> <p>1 in a real impurity present in a commercial 2 product. 3 I mean, it was during, you 4 know, the -- you know, the further -- or the 5 trial, you know, in order to further, or 6 trying to, you know, improve the quenching 7 process of irbesartan. 8 Q. And Mr. Lin, who was doing a 9 very good job at the time, said, if this is a 10 nitroso compound, we have a real problem 11 here, similar to the problem we have with 12 valsartan. 13 He was doing a good job, and 14 turned out in the end to have been the 15 correct person, right? 16 MR. GALLAGHER: Objection. 17 Compound, mischaracterizes testimony, 18 asked and answered. 19 A. Again, you know, as I said, at 20 least at that time or, you know, those guess 21 or projection, you know, as I indicated to 22 you, not all he said, you know, was correct, 23 okay? 24 Some he's making -- you know,</p> |

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| <p style="text-align: right;">Page 222</p> <p>1 he's, you know, guess, and he's also, you 2 know, particularly with regard to, you know, 3 the potential toxicity of the irbesartans, 4 that particular N-nitroso derivative of 5 irbesartan.</p> <p>6 You know, I don't think, you 7 know, it was appropriate for him to make that 8 judgment. You know, he is not a 9 toxicologist.</p> <p>10 MR. SLATER: Cheryll, let's go 11 to Exhibit 234, if we could, please, 12 which is the other document that was 13 provided in that Exhibit 288 to 14 Novartis by ZHP.</p> <p>15 That is not the document I was 16 expecting. I gave you the Bates 17 number. It should be the "Study 18 Report of Unknown Peak in Residual 19 Solvent of Valsartan."</p> <p>20 THE WITNESS: Okay.</p> <p>21 MR. SLATER: I'm talking to 22 Cheryll, though, but it's going to 23 come to you in a moment.</p> <p>24 THE WITNESS: Okay.</p> | <p style="text-align: right;">Page 224</p> <p>1 A. I went through this report, 2 yes.</p> <p>3 Q. Okay. And if we turn to the 4 next page, it's dated May 31, 2018, correct? 5 Do you see that?</p> <p>6 A. Yes.</p> <p>7 Q. If we turn to the next page, it 8 was actually signed off by several people, 9 including --</p> <p>10 MR. SLATER: If you could turn 11 to the next page, Cheryll. Thanks.</p> <p>12 Q. You see it was signed off by 13 multiple people, including Peng Dong, 14 correct?</p> <p>15 A. Mm-hmm.</p> <p>16 MR. SLATER: And now if we go 17 to the next page, please. Let's go 18 past the "Contents." I'm sorry. 19 Let's go to the "Background" section, 20 next page. So we're now on page 2 of 21 23.</p> <p>22 Q. So there's a "Background" 23 section of this report that talks about the 24 fact that there were many unknown peaks</p> |
| <p style="text-align: right;">Page 223</p> <p>1 MR. SLATER: One second. 2 Cheryll, what exhibit is this?</p> <p>3 MS. CALDERON: I have to check. 4 Give me one second.</p> <p>5 MR. SLATER: I had 234 on it. 6 I want to make sure we have it for the 7 record.</p> <p>8 MS. CALDERON: I'm not sure. I 9 have to look. It's not --</p> <p>10 MR. SLATER: I don't want to 11 waste any more time with this, so 12 let's just mark it again. What number 13 are we up to?</p> <p>14 THE STENOGRAPHER: 305. 15 (Whereupon, Exhibit Number 16 ZHP-305 was marked for 17 identification.)</p> <p>18 BY MR. SLATER:</p> <p>19 Q. Do you see what we've put up as 20 Exhibit 305, "Study Report of Unknown Peak in 21 Residual Solvent of Valsartan"?</p> <p>22 A. Mm-hmm.</p> <p>23 Q. You're familiar with this, 24 correct?</p> | <p style="text-align: right;">Page 225</p> <p>1 identified with the residual solvent for 2 valsartan with the Huahai method, correct?</p> <p>3 A. Yes, mm-hmm.</p> <p>4 Q. And just below that 5 "Background" section there's Figure 1, which 6 is titled as a "Typical chromatogram of 7 Huahai method."</p> <p>8 Do you see that?</p> <p>9 A. Mm-hmm.</p> <p>10 Q. What does that mean, "typical 11 chromatogram"?</p> <p>12 A. "Typical" usually means 13 representative, which means, you know, it can 14 be an example to illustrate.</p> <p>15 Q. And it says "FID." So is this 16 a gas chromatography-FID test?</p> <p>17 A. Yes.</p> <p>18 Q. And you can see a little better 19 on this -- rephrase.</p> <p>20 And you can see the peaks are 21 labeled, and the peak that's labeled farthest 22 to the right with a label is toluene.</p> <p>23 Do you see that?</p> <p>24 A. Yeah, mm-hmm.</p> |

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| <p style="text-align: right;">Page 226</p> <p>1 Q. And then there's a series of 2 unidentified smaller peaks to the right of 3 that?</p> <p>4 A. Yes.</p> <p>5 Q. And without figuring out which 6 one it is or exactly where it is, we know in 7 hindsight that the NDMA can be identified 8 there if one looks for it with gas 9 chromatography-mass spectrometry, correct?</p> <p>10 A. No, that's not correct.</p> <p>11 Q. If you were to be asked to go 12 and use GC-MS to look for NDMA, you don't 13 think you could identify it on this sample?</p> <p>14 A. GC-MS and GC-FID, they are two 15 different, quite different methods.</p> <p>16 Q. No, let me ask the question 17 differently, because that's not what I -- I 18 get why you're saying that, though.</p> <p>19 If one decided to test by GC-MS 20 instead of GC-FID, this batch, and actually 21 looked for NDMA, it would be able to be 22 identified with the GC-MS, correct?</p> <p>23 A. If you -- what we found out, 24 okay, if you just use, you know -- you know,</p> | <p style="text-align: right;">Page 228</p> <p>1 MR. GALLAGHER: Go ahead.</p> <p>2 A. You know, you know, I cannot 3 confirm, you know, the specific time range, 4 okay. But I can tell you, you know, just 5 look at this, you know, you know, Figure 1, 6 right.</p> <p>7 You know, basically after the 8 toluene peak, you have like three, right, 9 roughly three peaks, right? You see that?</p> <p>10 Three little peaks?</p> <p>11 Q. Yes.</p> <p>12 A. Right? Okay. As I, you know, 13 communicate, you know, to you earlier, the 14 first little peak appears to be -- okay, 15 there are two folds, okay.</p> <p>16 In the blank injection, there 17 was also a blank peak, okay, eluting at that 18 region, okay.</p> <p>19 With the real sample, at least 20 for some batches, okay, what we found is, you 21 know, this peak was n-butyl acetate, okay, 22 and then NDMA, you know, you know, it would 23 elute at the shoulder, you know, you know, 24 you know, of this peak. If you, you know,</p> |
| <p style="text-align: right;">Page 227</p> <p>1 basically if you use the conditions, right, 2 including the sample concentrations as in 3 this GC-FID method, if you then turn that 4 into a GC-MS method based upon our 5 retrospective, you know, analysis, you will 6 not be able to see NDMA, okay?</p> <p>7 And then I think that during 8 this investigation, the concentration of the 9 sample, you know, was increased by 20 times. 10 And even that, with the GC-MS chromatogram, 11 you know, you can see, you know, I think in 12 some of the figures, you know, I think in 13 some of the figures, you know, in this report 14 the NDMA peak was still not very obvious. It 15 was buried among other, you know, unknown 16 peaks.</p> <p>17 Q. The other night Qiangming Li 18 testified that the NDMA peak eluted on the 19 GC-FID between 14.2 and 14.5.</p> <p>20 Does that sound correct to you?</p> <p>21 A. I don't know. I mean, 22 because -- from --</p> <p>23 MR. GALLAGHER: Objection.</p> <p>24 THE WITNESS: Sorry.</p> | <p style="text-align: right;">Page 229</p> <p>1 making a reference then of NDMA with high 2 enough concentration, you know, it will, you 3 know, show a peak at that region.</p> <p>4 But with the regular batch, 5 basically, you know, the NDMA is just -- you 6 know, sometimes, you know, it just co-elute, 7 complete co-elute, sometimes may be a very 8 tiny, you know, shoulder peak there.</p> <p>9 Q. Solvias found it, right?</p> <p>10 A. They were using a quite 11 different, okay, method, okay. If you 12 notice, you know, one of the, you know, major 13 differences, they were using NMP as the 14 sample. You know, this particular method, 15 ZHP's method utilizing DMSO, okay.</p> <p>16 So when you use different 17 sample diluents, you will have different 18 background peaks, okay?</p> <p>19 So at that particular region, 20 when they turned that -- their NMP method 21 into the corresponding GC-MS method, and also 22 because, you know, the -- because NMP, you 23 know, is a higher-volume point as compared to 24 DMSO, right? So we did a comparison of the</p> |

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| <p>1 two methods.</p> <p>2 Their, you know, like</p> <p>3 incubation temperature, I think it was like</p> <p>4 at least 15 degrees Celsius higher, you know,</p> <p>5 you know, than the ZHP's method.</p> <p>6 So the bottom line is, you</p> <p>7 know, their GC-MS method appears to be more</p> <p>8 sensitive than ZHP's, you know, GC-MS method.</p> <p>9 Q. The point is, the technology</p> <p>10 and the methodology was clearly available to</p> <p>11 identify the NDMA, correct?</p> <p>12 A. Well, but first of all -- yes,</p> <p>13 the answer is yes, but, see, the first -- you</p> <p>14 know, you need to know what to look for,</p> <p>15 right? Yeah.</p> <p>16 Q. When you say "you need to know</p> <p>17 what to look for," you're talking about a</p> <p>18 risk assessment, right?</p> <p>19 A. Right.</p> <p>20 Q. And that's a very important</p> <p>21 part of testing, is that the risk assessment</p> <p>22 done as the threshold needs to be thorough,</p> <p>23 right?</p> <p>24 MR. GALLAGHER: Objection.</p> | <p>Page 230</p> <p>1 this particular case with Novartis, you know,</p> <p>2 they -- you know, in the very beginning, you</p> <p>3 know, they were raising some specific, you</p> <p>4 know, unknown impurities with a defined</p> <p>5 retention time. Okay.</p> <p>6 So throughout this process we</p> <p>7 have been working with Novartis, you know, to</p> <p>8 try to identify those little unknown peaks.</p> <p>9 Q. When you were working with</p> <p>10 Novartis to identify the peaks, did anybody</p> <p>11 from ZHP tell Novartis that you knew that</p> <p>12 NDMA is in the valsartan so that they would</p> <p>13 know to look for the NDMA?</p> <p>14 A. I don't think people involved,</p> <p>15 you know, in the communications, you know,</p> <p>16 directly with Novartis, you know, had that</p> <p>17 knowledge before the events.</p> <p>18 Q. Well, we know Peng Dong signed</p> <p>19 off on this unknown peak report, and he was</p> <p>20 on the e-mail in July of 2017, right?</p> <p>21 A. He was. But I don't know how</p> <p>22 much, you know, you know, you know, he really</p> <p>23 went through, or -- basically, you know, I</p> <p>24 didn't know what happened, you know, after</p> |
| <p>1 Vague.</p> <p>2 BY MR. SLATER:</p> <p>3 Q. I'll ask it differently.</p> <p>4 The risk assessment is the step</p> <p>5 that's taken before you do the testing so</p> <p>6 that you have thought through what you should</p> <p>7 be looking for, correct?</p> <p>8 A. The risk assessment is actually</p> <p>9 in the very beginning of the development of</p> <p>10 this particular valsartan process. So as a</p> <p>11 QC, you know, you know, as a daily QC</p> <p>12 operation, you don't do the risk, you know,</p> <p>13 you know, you know, assessment, you know, at</p> <p>14 that period.</p> <p>15 Q. Well, if you get back --</p> <p>16 rephrase.</p> <p>17 If you have a customer like</p> <p>18 Novartis that comes to you and says there's</p> <p>19 unknown peaks, part of the way you then try</p> <p>20 to study and figure out what those peaks are</p> <p>21 is to do a risk assessment to figure out what</p> <p>22 might they be so you know what you should</p> <p>23 look for, correct?</p> <p>24 A. Well, you know, you know, in</p> | <p>Page 231</p> <p>1 Mr. Lin, you know, sent out his e-mail.</p> <p>2 I mean, it looks like nobody</p> <p>3 responded to anything, so I don't know.</p> <p>4 People may just, as I said, for whatever the</p> <p>5 reason, there's no, you know, resonance, I</p> <p>6 will say.</p> <p>7 Q. With regard to the risk</p> <p>8 assessment that needed to be done -- well,</p> <p>9 rephrase.</p> <p>10 With regard to the risk</p> <p>11 assessment, you pointed out it's done in the</p> <p>12 very beginning when the process is developed.</p> <p>13 But that's also an ongoing process, risk</p> <p>14 assessment, during the lifecycle of the drug</p> <p>15 substance, correct?</p> <p>16 A. There is an ongoing, but</p> <p>17 usually with a particular, you know, you</p> <p>18 know, reason, yeah.</p> <p>19 Q. So, for example, where a</p> <p>20 customer says, there's unknown peaks, we want</p> <p>21 to know what these are, we want to know what</p> <p>22 these potential impurities are, that's a</p> <p>23 reason to perform a risk assessment in</p> <p>24 conjunction with the testing, right? That's</p> |

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| <p style="text-align: right;">Page 234</p> <p>1 good science, right?</p> <p>2 A. Well, based upon, you know, you</p> <p>3 know, you know, retrospective, you know, you</p> <p>4 know, communications, right. And the ZHP</p> <p>5 teams, you know, looks like, you know, focus</p> <p>6 on what the customer, you know, communicated,</p> <p>7 you know, to the team.</p> <p>8 Q. Well, what I'm asking is this.</p> <p>9 It's good science under these circumstances,</p> <p>10 where a customer reports unknown peaks and is</p> <p>11 concerned about impurities, to do a risk</p> <p>12 assessment, evaluate the chemical reactions</p> <p>13 that can occur, and have some idea of what</p> <p>14 you're looking for, right?</p> <p>15 That's good science, isn't it?</p> <p>16 A. Well, usually what happen,</p> <p>17 okay, when people, you know, you know -- you</p> <p>18 know, first of all, okay, for a -- like a</p> <p>19 residual solvent method, right, like a GC-FID</p> <p>20 method, there is no -- like a threshold for</p> <p>21 any unknown peak, you know, to be identified,</p> <p>22 even as of today. Okay.</p> <p>23 So when people talking about</p> <p>24 these small unknown peaks, you know, that's</p> | <p style="text-align: right;">Page 236</p> <p>1 they -- you know, as I said, like you said,</p> <p>2 you know, like Mr. -- although Mr. Peng Dong,</p> <p>3 you know, he was signing off and he was on</p> <p>4 the e-mail, but, you know, whatever, you</p> <p>5 know, for that reason, you know, basically,</p> <p>6 as I said, you know, Mr. Lin's e-mail just,</p> <p>7 you know, for whatever reason didn't</p> <p>8 generate, you know, any resonance.</p> <p>9 Q. Well, it generated a report</p> <p>10 that in April of 2018 you directed your team</p> <p>11 not to complete and not to issue because</p> <p>12 there was a sensitive impurity discussed.</p> <p>13 A. This impurity --</p> <p>14 MR. GALLAGHER: Objection.</p> <p>15 BY MR. SLATER:</p> <p>16 Q. Isn't that why it didn't</p> <p>17 resonate?</p> <p>18 MR. GALLAGHER: Objection.</p> <p>19 Outside the scope, mischaracterizes</p> <p>20 testimony, and mischaracterizes the</p> <p>21 document.</p> <p>22 A. As I indicated, you know, that</p> <p>23 impurity is completely different from NDMA.</p> <p>24 I mean, that's the N-nitroso derivative of</p> |
| <p style="text-align: right;">Page 235</p> <p>1 how people, you know, treated it, you know,</p> <p>2 initially as a technical issues, and so</p> <p>3 people focus on trying to resolve, you know,</p> <p>4 those identities, you know, to the customer.</p> <p>5 Because the customer wanted to</p> <p>6 have very specific answers, right, and so --</p> <p>7 you know, so from my, you know,</p> <p>8 understanding, you know, they -- at least at</p> <p>9 the time they were not requesting, you know,</p> <p>10 for anything other than they were, you know,</p> <p>11 you know, requested.</p> <p>12 So, yeah, so that's how, you</p> <p>13 know, the focus of the ZHP team basically,</p> <p>14 you know, just tried to, you know, meet, you</p> <p>15 know, the needs of the customer to get the</p> <p>16 answer to them as soon as -- you know, as</p> <p>17 they can.</p> <p>18 Q. The quickest way to get the</p> <p>19 answer to Novartis would have been to tell</p> <p>20 them that there was NDMA in the valsartan,</p> <p>21 right?</p> <p>22 A. As I said, the team, you know,</p> <p>23 you know, the people involved, you know,</p> <p>24 directly with the communication, you know,</p> | <p style="text-align: right;">Page 237</p> <p>1 irbesartan, so it's completely different.</p> <p>2 BY MR. SLATER:</p> <p>3 Q. Before we go back into this</p> <p>4 report, I just want to make sure we're on the</p> <p>5 same page.</p> <p>6 The assessment of the potential</p> <p>7 explanation for the impurities involves a</p> <p>8 chemical analysis, right? You have to do</p> <p>9 that analysis as part of the testing process,</p> <p>10 right?</p> <p>11 A. No. Well, typically you do a</p> <p>12 mechanistic analysis, you know, based upon</p> <p>13 that mechanistic analysis or based upon the</p> <p>14 knowledge when this particular process was</p> <p>15 developed, right.</p> <p>16 And if the analysis, you know,</p> <p>17 indicate there's some level of risk, then you</p> <p>18 will follow up to do a -- what is called a</p> <p>19 confirmatory testing.</p> <p>20 But if the risk assessment, you</p> <p>21 know, at that time, or if the knowledge, you</p> <p>22 know, because of the knowledge gap, you know,</p> <p>23 it didn't turn up as a risk, you -- you know,</p> <p>24 you would not necessarily, you know, to do,</p> |

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| <p>Page 238</p> <p>1 you know, you know, an analysis. 2 Q. Was CEMAT doing this testing 3 that's represented in this unknown peak 4 study? 5 A. This particular work, you know, 6 in this report, okay, it was done, you know, 7 you know, you know, by the QC as well as, you 8 know, with, you know, CEMAT, yes. So it's a 9 combination, yes. 10 Q. Were you involved? 11 A. I was not directly involved. 12 Q. Did you have visibility to it? 13 Were you aware of what was being done? 14 A. Well, only at the time, you 15 know, they couldn't figure out, you know, 16 some identities, you know, of a particular 17 unknown peak, then they will come to me, you 18 know, asking for possible solutions. 19 Yeah, I did help him, you know, 20 provided some strategies, you know, to help 21 him -- to help them, you know, getting, you 22 know, the elucidation of some, you know, 23 unknown peaks. 24 Q. And what strategies did you</p> | <p>Page 240</p> <p>1 originated from DMSO or it's originated from 2 some other reasons. 3 MR. SLATER: Cheryll, let's go 4 in this report to page 19 of 23, 5 please. Or not. 6 MS. CALDERON: You know what? 7 MR. SLATER: Frozen? 8 MS. CALDERON: I am frozen. 9 Can you hear me? 10 MR. SLATER: Yes. 11 MS. CALDERON: Okay. Can you 12 repeat what you said? Because I 13 froze. 14 MR. SLATER: Sure. If you 15 could turn to page 19 of 23, please. 16 MS. CALDERON: Okay. Sorry. 17 MR. SLATER: No problem. The 18 thing doesn't want to move. 19 THE WITNESS: It's getting 20 late. 21 MR. SLATER: It's worn out. 22 MS. CALDERON: Let me restart. 23 MR. SLATER: I think you were 24 there. Oh, okay.</p> |
| <p>Page 239</p> <p>1 help with? 2 A. One of the strategy that I told 3 him to use is to use butyrate DMSO. 4 The reason for that is, you 5 know, quite a few of those interfering or 6 background peaks, they were minor degradation 7 products of DMSO, okay, with this particular 8 method because DMSO, you know, you know, 9 retrospectively that we found that, you know, 10 it -- or during the process of this 11 investigation we found out it will decompose 12 to give, you know, a number of, you know, 13 minor degradants. 14 I think some of those are, you 15 know, you know, mentioned in the reports, 16 like dimethyl, you know, you know, sulfide or 17 dimethyl disulfide. 18 So the reason that I suggest 19 them to use butyrate one is that, you know, 20 you know, based upon the GC-MS analysis, you 21 can -- if you see any peak, right, with what 22 we call the mass shift, okay, and then we can 23 basically, you know, understand, you know, 24 the origin of that unknown peak, whether it's</p> | <p>Page 241</p> <p>1 MS. CALDERON: How's that? 2 MR. SLATER: I'll let you know 3 when it comes up. 4 Perfect. Scroll up a little 5 tiny bit more, get the whole risk 6 assessment in there. Perfect. 7 BY MR. SLATER: 8 Q. This study report of unknown 9 peaks from May of 2018 contains a Risk 10 Assessment here on page 19. 11 Do you see that? 12 A. Mm-hmm. 13 Q. And the Risk Assessment says, 14 "It is shown from above, each unknown peak 15 has either been identified or the source of 16 which identified, and the results are far 17 lower than the specification by quantitative 18 analysis." I want to stop there. 19 The reference to 20 "specification" has to do with already 21 identified solvents or other substances that 22 you already know may be there, correct? 23 A. In this particular case, yes. 24 It looks like utilizing 10 percent of the</p> |

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| <p style="text-align: right;">Page 242</p> <p>1 toluene ICH, you know, standard.</p> <p>2 Q. And it says, "Control of these</p> <p>3 unknown peaks by comparing to the peak area</p> <p>4 of 10 percent toluene (ICH limit 89 parts per</p> <p>5 million) presents no risk." And then it</p> <p>6 says, "Please refer to the following table</p> <p>7 for details."</p> <p>8 I want to stop there. When it</p> <p>9 refers to 89 parts per million presenting no</p> <p>10 risk, is that a judgment that was made that</p> <p>11 as long as something that's not identified is</p> <p>12 less than 89 parts per million, you don't</p> <p>13 have to worry about it?</p> <p>14 A. Well, this 89 percent numbers</p> <p>15 or criteria, based upon, you know, what I was</p> <p>16 told, you know, it came from one of Novartis'</p> <p>17 document.</p> <p>18 So basically during -- in our</p> <p>19 conversation, you know, at least at one time,</p> <p>20 the Novartis practice was that, you know, at</p> <p>21 that time, you know, you do not necessarily</p> <p>22 need to investigate any unknown peaks, okay,</p> <p>23 with peak area lower than toluene, you know,</p> <p>24 standard of -- you know, or toluene, you</p> | <p style="text-align: right;">Page 244</p> <p>1 the conclusion on page 23 of 23. Can</p> <p>2 you scroll up just a little bit just</p> <p>3 so we capture the bottom of the</p> <p>4 conclusion, please? Perfect.</p> <p>5 Q. The conclusion of the report</p> <p>6 repeats the risk assessment, saying that "The</p> <p>7 unknown peaks can be controlled by comparing</p> <p>8 to the peak area of 10 percent toluene, ICH</p> <p>9 limit (89 parts per million). The product</p> <p>10 quality is less likely to be impacted."</p> <p>11 Same conclusion as the risk</p> <p>12 assessment, right?</p> <p>13 A. Mm-hmm, yes.</p> <p>14 Q. Now, in retrospect, there was</p> <p>15 NDMA there, and that was affecting the</p> <p>16 quality of the product, right?</p> <p>17 A. Yes. But here, you know, the</p> <p>18 subject of this investigation, you know,</p> <p>19 would focus on that nine, you know, unknown</p> <p>20 peaks. So that conclusion was made based</p> <p>21 upon assessment of those nine unknown peaks.</p> <p>22 So NDMA was not among one of them.</p> <p>23 Q. Okay. Well, when you say NDMA</p> <p>24 was not among them, NDMA was not being looked</p> |
| <p style="text-align: right;">Page 243</p> <p>1 know, reference solution has 89, you know,</p> <p>2 ppm concentrations.</p> <p>3 Q. Coming back to my question, it</p> <p>4 appears to me the risk assessment was as long</p> <p>5 as an unknown peak is less than 89 parts per</p> <p>6 million, there's no risk; you don't have to</p> <p>7 be concerned about it even if you can't</p> <p>8 identify what it is.</p> <p>9 Do I understand that correctly?</p> <p>10 A. No. That's not what it says.</p> <p>11 I mean, basically, you know, it looks like</p> <p>12 whoever made that risk assessment, you know,</p> <p>13 people utilized, you know, what Novartis at</p> <p>14 least, you know, you know, had done, you</p> <p>15 know, at one point.</p> <p>16 Because even as of today, you</p> <p>17 know, as to what a threshold, you know, you</p> <p>18 need to identify for unknown peaks with</p> <p>19 GC-FID method. Is still -- there's no fixed</p> <p>20 answer to that.</p> <p>21 Q. Well, the answer is that the</p> <p>22 NDMA -- well, rephrase. We'll come back to</p> <p>23 it.</p> <p>24 MR. SLATER: Let's go now to</p> | <p style="text-align: right;">Page 245</p> <p>1 for because nobody actually said we need to</p> <p>2 look for NDMA, right?</p> <p>3 A. Well, whoever -- you know, you</p> <p>4 know, people doing this particular, you know,</p> <p>5 or people -- I mean, particularly the main --</p> <p>6 you know, the main author, right, you know,</p> <p>7 of this investigation, he had no knowledge.</p> <p>8 Q. And he didn't -- he didn't do</p> <p>9 or didn't have available to him a risk</p> <p>10 assessment advising of the potential</p> <p>11 development of NDMA, right? That was not</p> <p>12 provided, correct?</p> <p>13 A. I don't know whether, you know,</p> <p>14 somebody provide it or not. But based upon,</p> <p>15 you know, what's presented here, you know, it</p> <p>16 looks like the risk assessment was solely</p> <p>17 based upon, you know, that nine unknown</p> <p>18 peaks.</p> <p>19 Q. And the person who authored</p> <p>20 this report certainly didn't document knowing</p> <p>21 what was known by others in the company, that</p> <p>22 there was NDMA in the drug substance,</p> <p>23 correct?</p> <p>24 A. As I said, you know, the main</p> |

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| <p>1 author, he had no knowledge.</p> <p>2 MR. SLATER: Why don't we go</p> <p>3 off the record for a second.</p> <p>4 THE VIDEOGRAPHER: The time</p> <p>5 right now is 12:13 p.m. We're now off</p> <p>6 the record.</p> <p>7 (Whereupon, a recess was</p> <p>8 taken.)</p> <p>9 THE VIDEOGRAPHER: The time</p> <p>10 right now is 12:26 p.m. We're back on</p> <p>11 the record.</p> <p>12 BY MR. SLATER:</p> <p>13 Q. So we have on screen</p> <p>14 Exhibit 213, which is an FDA Warning Letter</p> <p>15 dated November 29, 2018.</p> <p>16 Do you see that?</p> <p>17 A. Mm-hmm.</p> <p>18 Q. And you understand this warning</p> <p>19 letter followed from the FDA inspection from</p> <p>20 July 23 to August 3 at ZHP's facilities,</p> <p>21 correct?</p> <p>22 MR. GALLAGHER: Objection.</p> <p>23 Outside the scope.</p> <p>24 You can answer to the extent</p> | <p>Page 246</p> <p>1 Q. The FDA advised your company,</p> <p>2 "Our investigators also noted other examples</p> <p>3 of your firm's inadequate investigation of</p> <p>4 unknown peaks observed in chromatograms."</p> <p>5 I want to stop there. That's</p> <p>6 what we were just talking about, is ZHP's</p> <p>7 study report on unknown peaks in May of 2018,</p> <p>8 correct?</p> <p>9 A. I'm sorry, say that again?</p> <p>10 Q. We were just discussing the</p> <p>11 study report of unknown peaks in residual</p> <p>12 solvent of valsartan a few moments ago,</p> <p>13 correct?</p> <p>14 A. Right, mm-hmm.</p> <p>15 Q. And here the FDA's pointing out</p> <p>16 that they thought that the investigation of</p> <p>17 unknown peaks observed in chromatograms was</p> <p>18 inadequate.</p> <p>19 That's what the FDA found,</p> <p>20 correct?</p> <p>21 A. That's what they statement. I</p> <p>22 think we had a -- you know, an explanation</p> <p>23 and a response.</p> <p>24 Q. This points out, "For example,</p> |
| <p>1 you know personally.</p> <p>2 A. Well, that I know, it's issued</p> <p>3 after the inspection.</p> <p>4 Q. Right. And you can see in the</p> <p>5 first paragraph the dates of the inspection</p> <p>6 were July 23 to August 3, 2018.</p> <p>7 Do you see that?</p> <p>8 A. Yeah, mm-hmm.</p> <p>9 Q. So if we scroll down a little</p> <p>10 further down on this page, deviation number 1</p> <p>11 is titled, "Failure of your quality unit to</p> <p>12 ensure that quality-related complaints are</p> <p>13 investigated and resolved." Right?</p> <p>14 A. I saw the title.</p> <p>15 MR. SLATER: Let's go down to</p> <p>16 the next page and look at part of what</p> <p>17 was discussed somewhat relevant to</p> <p>18 what we just talked about.</p> <p>19 You can scroll down further,</p> <p>20 Cheryll, because I want to -- that's</p> <p>21 good right there. Thank you.</p> <p>22 Q. So you see a paragraph that</p> <p>23 starts with the word "Our investigators"?</p> <p>24 A. Mm-hmm.</p> | <p>Page 247</p> <p>1 valsartan intermediates," and it gives some</p> <p>2 numbers of those batches, "failed testing for</p> <p>3 an unknown impurity (specification less than</p> <p>4 or equal to 0.5 percent) with results of</p> <p>5 0.56 percent for both batches. Your action</p> <p>6 plan indicated that the impurity would be</p> <p>7 identified as part of the investigation;</p> <p>8 however, you failed to do this."</p> <p>9 A. No, we did that, actually. We</p> <p>10 did afterward. I mean, at the time of this</p> <p>11 warning letter, you know, the investigation,</p> <p>12 I think, was still ongoing, okay.</p> <p>13 So actually as part of the --</p> <p>14 you know, of the CAPA or the commitment, you</p> <p>15 know, we actually, you know, did an</p> <p>16 investigation, but we didn't resolve, you</p> <p>17 know, the whole structure, okay.</p> <p>18 And we, you know, you know, we</p> <p>19 told the, you know, the investigator, you</p> <p>20 know, this is a process impurity, you know,</p> <p>21 structurally related to that of valsartan</p> <p>22 intermediate. But we didn't know its exact</p> <p>23 structure, right?</p> <p>24 So, yeah, so the investigation</p> |

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| <p style="text-align: right;">Page 250</p> <p>1 was ongoing, and eventually, you know, we 2 resolved, you know, you know, that structure, 3 okay.</p> <p>4 Q. You said you resolved that 5 structure.</p> <p>6 A. Right.</p> <p>7 Q. You mean you find NDMA?</p> <p>8 A. Yes, finally with NMR we were 9 able to identify those structures, yes, and 10 which is confirmed it is a process-related, 11 you know, impurity of that intermediate.</p> <p>12 Q. But by this time it was already 13 identified as NDMA, right?</p> <p>14 A. You mean by the time of -- 15 yeah, of this warning letter, yeah. NDMA, 16 yes, that already was identified. But this 17 is -- you know, FDA was talking about, you 18 know, this is, you know, a completely 19 different impurity. Yeah.</p> <p>20 Q. What do you mean, the FDA's 21 saying it's a completely different impurity?</p> <p>22 A. Well, you know, here they 23 specifically pointing out to -- you know, to 24 that, you know, particular impurity, you</p> | <p style="text-align: right;">Page 252</p> <p>1 particular impurity, and also I think we did 2 the assessment at the time, this impurity is 3 just not -- you know, actually was not being 4 carried over into the downstream product, 5 right?</p> <p>6 So, therefore, you know, the 7 risk was, you know, was very limited or 8 negligible. So that's how, you know, QA 9 decided, you know, to, you know, basically to 10 close the main investigation, but with a 11 follow-up, you know, cover. Okay. That's a 12 very typical, you know, way, you know, you 13 know, in the industry, you know, to do those, 14 like, impurity related, you know, 15 investigation.</p> <p>16 Q. Well, the FDA didn't seem happy 17 with status of the investigation.</p> <p>18 A. Well, that's -- I think that's 19 their, you know, misunderstanding, you know, 20 from my perspective.</p> <p>21 So I think, as I said, during 22 the final meetings or the last meeting, you 23 know, being on-site at FDA, and also in our 24 follow-up, you know, responses, you know, we</p> |
| <p style="text-align: right;">Page 251</p> <p>1 know, given a value of 0.56 percent, right? 2 Yeah. So, yeah, so that's not an NDMA or any 3 other nitroso, you know, compound.</p> <p>4 Q. So coming back to the FDA's 5 comments, they're indicating that -- 6 rephrase.</p> <p>7 Coming back to the FDA's 8 warning letter, the FDA stated your action 9 plan, that would be ZHP's action plan, given 10 on a prior date, correct?</p> <p>11 A. Yeah, our plan is, you know, we 12 will continue, you know, to do, you know, the 13 structure elucidation, okay.</p> <p>14 Basically, you know, as part 15 of, like, this OOS investigation, okay, 16 although, you know, we tried to identify 17 unknown peaks as soon, you know, or as 18 quickly as possible, but sometimes, you know, 19 an unknown peak, you know, structure takes 20 time, right.</p> <p>21 So during that kind of, you 22 know, you know, situation, what you can do 23 is, you know, basically once we know, you 24 know, you know, the basic information of this</p> | <p style="text-align: right;">Page 253</p> <p>1 stated very clearly, you know, you know, to 2 the FDA, you know, this follow-up action has 3 been completed. Yeah.</p> <p>4 Q. The FDA continues to state, 5 "Additionally, residual solvent chromatograms 6 for valsartan API validation batches 7 manufactured using your zinc chloride 8 process, with DMF in 2012," and then it gives 9 the three validation batch numbers, "show at 10 least one unidentified peak eluting after the 11 toluene peak in the area where the presence 12 of NDMA was suspected to elute."</p> <p>13 A. Again, you know, this peak, as 14 I indicated to you, based upon our 15 retrospective analysis, that first, you know, 16 you know, visible, you know, small peaks 17 based upon our investigation, it was n-butyl 18 acetate.</p> <p>19 Q. And I think you explained the 20 NDMA was right next to that.</p> <p>21 A. It's on the shoulder. As I 22 said, after if we inject it with a, you know, 23 a more concentrated sample, like a pure 24 sample, right, and -- you know, then we would</p> |

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| <p>Page 254</p> <p>1 find out.</p> <p>2 But in the chromatogram of a</p> <p>3 real sample, right, you know, like we analyze</p> <p>4 using the GC-FID method.</p> <p>5 To analyze a real sample, the</p> <p>6 NDMA peak was basically, you know, submerged</p> <p>7 with, overwhelmed by this, you know,</p> <p>8 proceeding peak which is the n-butyl acetate.</p> <p>9 Q. As a matter of good</p> <p>10 manufacturing practices, it's not acceptable</p> <p>11 to do a test, not identify the peak, and just</p> <p>12 say, well, it's pretty small, so we don't</p> <p>13 really have to worry about identifying it.</p> <p>14 That's not acceptable, right?</p> <p>15 MR. GALLAGHER: Objection.</p> <p>16 Vague, and calls for speculation.</p> <p>17 A. We follow ICH guidance, okay,</p> <p>18 in terms of, you know, what needs to be</p> <p>19 identified, what -- you know, you know, you</p> <p>20 do not necessarily need to identify it.</p> <p>21 BY MR. SLATER:</p> <p>22 Q. It's not acceptable where</p> <p>23 you're trying to identify what an unknown</p> <p>24 peak is to run your standard test, not</p> | <p>Page 256</p> <p>1 So its intended purpose is not</p> <p>2 to, you know, identify, you know, any little,</p> <p>3 you know, you know, unknown peaks, right?</p> <p>4 So, you know, and once again,</p> <p>5 as I mentioned, even as of today, in ICH Q3C,</p> <p>6 which is the most relevant ICH guidance</p> <p>7 governing the residual solvent, okay, even in</p> <p>8 that guidance today there is no specific</p> <p>9 requirement in terms of, you know, above what</p> <p>10 threshold an unknown peak need to be</p> <p>11 identified.</p> <p>12 Q. One of the things that you need</p> <p>13 to know as a drug manufacturer is the</p> <p>14 limitations of GC-FID.</p> <p>15 That's one thing you need to be</p> <p>16 aware of, right?</p> <p>17 A. Well, it's all depends upon</p> <p>18 what's the intended purpose, right? So with</p> <p>19 the intended purpose for the residual</p> <p>20 solvents, the GC-FID method is perfectly</p> <p>21 suitable for that purpose.</p> <p>22 Q. Well -- rephrase.</p> <p>23 Here you had unknown peaks,</p> <p>24 didn't know what they were, according to the</p> |
| <p>Page 255</p> <p>1 identify it, and just assume it's fine,</p> <p>2 because you know that even something with a</p> <p>3 very, very small peak, something that's</p> <p>4 barely perceptible, if it's a</p> <p>5 mutagenic/genotoxic impurity, that can be</p> <p>6 dangerous and can't be in the product, right?</p> <p>7 MR. GALLAGHER: Objection.</p> <p>8 Vague, lacks foundation, and compound.</p> <p>9 A. You know, for those very</p> <p>10 low-level potential genotoxic impurity, you</p> <p>11 would need to develop a specific method,</p> <p>12 okay, to -- you know, to detect them, to</p> <p>13 control them, okay.</p> <p>14 For any other method, right,</p> <p>15 like, for example, this residual solvent</p> <p>16 method, they just are not adequate, okay, to</p> <p>17 look for those unknown peaks, okay.</p> <p>18 Time again, you know, I mean,</p> <p>19 you know, based upon our retrospective</p> <p>20 investigation, you know, the GC-FID method is</p> <p>21 just -- you know, its intended -- its</p> <p>22 original intended purpose is to monitor those</p> <p>23 residual solvents. That's its intended</p> <p>24 purpose.</p> | <p>Page 257</p> <p>1 documents, and made a decision, it's a low</p> <p>2 amount, we don't have to be concerned.</p> <p>3 That was the decision that was</p> <p>4 made, right?</p> <p>5 A. Look, as I -- once again, you</p> <p>6 know, with the GC-FID method, okay, if you go</p> <p>7 into any pharmaceutical company, okay,</p> <p>8 including like my former, you know, employer,</p> <p>9 right, Merck & Company or any other, you</p> <p>10 know, like Schering-Plough, you know, these</p> <p>11 are the very famous, you know, multinational</p> <p>12 companies, okay, you know, people will not --</p> <p>13 you know, for a residual solvent method, they</p> <p>14 will not going through every tiny little</p> <p>15 peaks to identify, you know, what they are,</p> <p>16 okay, you know, at least, you know, you know,</p> <p>17 before, you know, that event came out, right?</p> <p>18 So -- so basically, you know,</p> <p>19 as I said, you know, it's -- you know, you</p> <p>20 will need to know, okay, and also it need to</p> <p>21 be above -- you know, like, for example, like</p> <p>22 in our conversation with Novartis or with</p> <p>23 some other, you know, you know, customers,</p> <p>24 right, they were, you know, also, at least</p> |

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| <p style="text-align: right;">Page 258</p> <p>1 some of them, they were not sure, you know, 2 what a specific threshold, you know, it need 3 to be set.</p> <p>4 So, but from our perspective, 5 if customer had that particular request for 6 certain specific, you know, unknown peaks, 7 yeah, we will do the investigation and try 8 to, you know, identify or try to find, you 9 know, the potential source, you know, you 10 know, for those unknown peaks.</p> <p>11 Q. It sounds like you're telling 12 me it's really hard to find it, but Novartis, 13 plus using an outside lab, they found the 14 NDMA, and it wasn't even their drug 15 substance. They found it before ZHP did on 16 these chromatograms, is what you're -- and 17 you're telling me it was too hard to figure 18 it out?</p> <p>19 A. Yes. Don't forget, these are 20 the two different methods, okay? Two 21 different methods, you know, you know, their 22 critical, you know, method parameters, they 23 are quite different. Okay.</p> <p>24 Even for GC-FID, if you run on</p> | <p style="text-align: right;">Page 260</p> <p>1 question, Novartis, enlisting the help of an 2 outside lab, identified the NDMA, right? It 3 wasn't so hard to do. They did it, right?</p> <p>4 A. Look, we supplied Novartis, 5 right, you know, all material like commercial 6 skill batches, at least, you know, by the end 7 of 2017, right. And they received, you know, 8 a lot of those.</p> <p>9 So from there, you know, I 10 mean, I don't know why they, you know, you 11 know, sended it to the outside lab or 12 whatever.</p> <p>13 So at least, you know, they -- 14 usually, when you go into business trying to 15 have a new, you know, vendor, you know, you 16 will do the analysis or in-depth, you know, 17 you know, analysis, you know, for the sample 18 that you're going to be for your commercial, 19 you know, productions.</p> <p>20 So during that period, you 21 know, Novartis, you know, their own lab, you 22 know, still not was able to find. So my 23 guess is, you know, once they contract this 24 out to a certain lab, they just happen to be,</p> |
| <p style="text-align: right;">Page 259</p> <p>1 different instrument, sometimes, you know, 2 the sensitivity can be vary quite a bit.</p> <p>3 Okay.</p> <p>4 So, you know, and also, you 5 know, some of our customer, they had a, you 6 know, similar question regarding the unknown 7 peaks, right? They also did a GC-MS 8 analysis. Okay, they didn't, you know, find, 9 you know, you know, NDMA.</p> <p>10 I mean, and also we supply, you 11 know, our product, right, with the zinc 12 chloride. You know, I think shortly after 13 the zinc chloride, you know, was approved by, 14 you know, regulators, right, we supplied to 15 Novartis', you know, subsidiary company, 16 Sandoz, right. Sandoz, at least at that 17 time, was part of Novartis.</p> <p>18 So we supply Sandoz valsartan 19 for quite, you know, long period. And so as 20 a unit of Novartis, you know, they haven't 21 had any, you know, you know, issues, or 22 didn't, you know, even have questions, I 23 think, as far as I understand, okay.</p> <p>24 Q. Just to get back to my</p> | <p style="text-align: right;">Page 261</p> <p>1 you know, utilizing a different, you know, 2 you know, method.</p> <p>3 Okay. That method, it appears 4 to be, you know, somewhat more sensitive than 5 ZHP's method. Okay.</p> <p>6 So if we -- you know, if 7 someone would keep using that -- you know, 8 you know, that condition that's originally 9 intended for the GC-FID, you know, I think 10 it's very fair to say, you know, NDMA, you 11 know, at the -- you know, the level that's 12 produced or that's present, you know, you 13 know, you know, in ZHP's batches, you know, 14 it was very difficult, if not entirely 15 possible, I mean, to be adequately detected. 16 Okay.</p> <p>17 Q. You're aware that starting in 18 2014, complaints came in on a pretty regular 19 basis from your customers pointing out 20 unknown peaks and asking for answers.</p> <p>21 You do know that there were 22 multiple complaints and requests for 23 information, right?</p> <p>24 MR. GALLAGHER: Objection.</p> |

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| <p style="text-align: right;">Page 262</p> <p>1 Vague, and lacks foundation. 2 You can answer. 3 A. Yeah. I mean -- yeah, I mean, 4 retrospectively, you know, you know, for 5 some -- you know, you know, during the later 6 stage of the investigation, you know, you 7 know, yeah.</p> <p>8 For example, with Novartis, 9 also with Sun Pharma at the time, yeah, I 10 was -- you know, later was also being 11 consulted, you know, you know, how to, you 12 know, address the origin or the identity.</p> <p>13 But essentially, you know, it's 14 the same set of the, you know, phenomenon, 15 right? And so my guess is, you know, in our 16 registered DMF or whatever, you know, the 17 other kind of dossier, you know, you know, we 18 just supplied to those customers, right, 19 within -- you know, using the same set of 20 documents, right?</p> <p>21 And in those, you know, 22 regulatory approved documents, you know, 23 there was no, you know, specific information 24 about, you know, some of those peaks. So</p> | <p style="text-align: right;">Page 264</p> <p>1 BY MR. SLATER: 2 Q. Coming back to my question, 3 you're aware that there were multiple 4 complaints made by customers in 2014, 2015, 5 2016, 2017, and 2018, saying that there were 6 unknown peaks on their own testing, and they 7 were looking for answers from ZHP as to what 8 was the cause of those peaks. 9 That's a correct statement, 10 right?</p> <p>11 MR. GALLAGHER: Objection. 12 Lacks foundation.</p> <p>13 THE WITNESS: Sorry. 14 MR. GALLAGHER: Go ahead.</p> <p>15 A. As I indicated, I didn't know, 16 or I was not informed, you know, initially. 17 And in some of those conversations, you know, 18 late in the investigation, as I said, I was 19 being consulted, you know, you know, or I was 20 trying -- you know, they tried to pull me to 21 help them to find out, you know, you know, 22 the identity or the potential sources.</p> <p>23 BY MR. SLATER: 24 Q. All I'm asking is to confirm --</p> |
| <p style="text-align: right;">Page 263</p> <p>1 that's why, you know, you know, some people, 2 you know, they turn out to be having, you 3 know, the same kind of question.</p> <p>4 But again, you know, you know, 5 based upon my, you know, knowledge, you know, 6 first of all, you know, they -- initially at 7 least, they all concentrated on relatively 8 large peaks. And they ask for a certain 9 specific, you know, set of peaks, right, and 10 then we work with them, you know.</p> <p>11 And also for some of the later 12 coming in, you know, questions, we would 13 sometimes utilize, you know, the previously, 14 you know, obtained results to help answer.</p> <p>15 For example, like in Novartis' 16 cases, like I think we utilized some of the 17 results, you know, we provided to Sun Pharma.</p> <p>18 And again, you know, some of 19 those companies, they have been, you know, 20 continuously, you know, you know, you know, 21 buying, you know, commercial batches of -- 22 you know, of, you know, valsartan, up to a 23 point that, you know, we sent out the notice, 24 you know, for suspension and also for recall.</p> | <p style="text-align: right;">Page 265</p> <p>1 rephrase. 2 All I'm looking to confirm 3 right now is -- rephrase. 4 You can confirm for me that 5 starting in 2014 with Ranbaxy and Sun Pharma, 6 then Vertex, then Glenmark, then Sun Pharma, 7 then Aurobindo, then Novartis, from 2014 to 8 2018, there were repeated customer complaints 9 pointing to unknown peaks, correct?</p> <p>10 MR. GALLAGHER: Objection. 11 Vague, lacks foundation, asked and 12 answered.</p> <p>13 A. Some of those, they were 14 treated as technical, you know, exchange, 15 okay? And some of the customer, you know, 16 you know, you know, at the time they, you 17 know, they have this question, they were 18 already, you know, receiving our commercial, 19 you know, batches, as far as I know.</p> <p>20 So they just wanted to know a 21 little bit further, you know, the identity 22 of, as I said, a certain specific numbers of 23 unknown peaks. Okay.</p> <p>24 Every time -- I mean, you know,</p> |

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| <p>1 basically they are the same set of the 2 unknown peaks, right? 3 And as I said, you know, the 4 reason why different company ask, you know, 5 those questions is, my guess is probably 6 because, you know, in our, you know, official 7 documents, right, like the DMF or some other, 8 you know, regulatory approved documents, you 9 know, in there, there was, you know, no 10 information on some of those, like, very 11 small peaks. So -- you know, so, yes. 12 So it's the same kind of 13 questions, and every time, as I said, we 14 tried to do, you know, what we can to 15 identify these peaks. 16 I think, you know, in the end, 17 you know, we -- for all of the concerned 18 peaks, you know, I think, you know, we were 19 able to find the identity or the potential 20 sources.</p> <p>21 Q. You realize these companies 22 that were complaining to ZHP about these 23 unknown peaks, they weren't asking for the 24 information because they were curious. They</p> | <p>Page 266</p> <p>1 get the results, you know, they need like 2 very -- you know, very quickly. 3 But, you know, again, as I 4 said, those regulatory document, you know, we 5 have the agency or regulatory, you know, 6 approve the specification at the time. 7 BY MR. SLATER: 8 Q. The responsibility for the 9 quality of the valsartan API was ZHP's 10 responsibility, right? 11 A. Yes. 12 Q. And despite -- rephrase. 13 Despite that, Novartis 14 identified the NDMA before ZHP did in 15 June 2018, right? 16 A. It's the third-party lab, okay, 17 and they -- you know, initially, you know, 18 they tentatively identified, and they 19 communicated it to us. 20 And upon the receipt of the 21 information, we immediately, you know, 22 purchased the reference materials, developed 23 method, and -- yeah, so we very quickly 24 confirmed their results.</p> |
| <p>1 were asking what those peaks represented 2 because they had quality obligations and GMP 3 obligations and wanted to make sure that the 4 substance they were purchasing from ZHP met 5 the quality standards and was safe. 6 That's why they were asking, 7 right?</p> <p>8 MR. GALLAGHER: Objection. 9 Lacks foundation, and calls for 10 speculation.</p> <p>11 A. It's a continuous process for 12 improvement. And, you know, that's why, you 13 know, you know, we understand our customers' 14 concerns, right?</p> <p>15 That's why every time, you 16 know, they have a question, we responded, you 17 know, and we trying to resolve, you know, the 18 issue as well as, you know, possible.</p> <p>19 And particularly during my, you 20 know, you know, review of some of the 21 documents, you know, with Novartis, you know, 22 I think like in late May 2018, you know, 23 there's one e-mail from Novartis, you know, 24 they -- you know, they thank us, you know, to</p> | <p>Page 267</p> <p>1 And also, within a very short 2 period of time, we developed an adequate 3 quantitative methods. So we will be able 4 to very quickly to come up with, you know, 5 you know, quite reliable NDMA results, okay, 6 in those, you know, batches, particularly 7 those batches, you know, you know, we 8 discussed with Novartis. 9 Q. Well, just to be clear, ZHP 10 already knew that the NDMA was in the 11 valsartan, we've already established that, at 12 least as of July 2017. 13 A. As I told you, at that time, 14 you know, Mr., you know, Lin's, you know, 15 e-mail, you know, as I said, it looks like 16 didn't go far. 17 So company as a whole, you 18 know, it didn't have that knowledge until, 19 you know, receiving that Novartis, you know 20 e-mails. 21 Q. Well, what happened was 22 Novartis figured out that there was NDMA 23 there, enlisting the services of a 24 third-party lab to help it, and then</p> |

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| <p style="text-align: right;">Page 270</p> <p>1 basically told ZHP that ZHP needed to take 2 the steps to notify the authorities and take 3 steps to deal with the severe quality 4 problem.</p> <p>5 That's the only reason ZHP told 6 anybody what happened here, was because 7 Novartis pushed you to do it, right?</p> <p>8 A. No.</p> <p>9 MR. GALLAGHER: Objection. 10 Vague, lacks foundation.</p> <p>11 BY MR. SLATER:</p> <p>12 Q. If Novartis had not come along, 13 there's no reason to believe that ZHP would 14 have told anybody about the NDMA, right?</p> <p>15 MR. GALLAGHER: Objection. 16 A. That's your speculation. 17 MR. GALLAGHER: Lacks 18 foundation.</p> <p>19 BY MR. SLATER:</p> <p>20 Q. We know that in July of 2017, 21 it was discussed in an e-mail that valsartan 22 had NDMA in it, and ZHP didn't tell anybody 23 about that, right?</p> <p>24 A. My answer -- you know, I think</p> | <p style="text-align: right;">Page 272</p> <p>1 You certainly would agree with 2 me that the FDA's right; that you stopped 3 your investigation before figuring out the 4 answer, and then it was only when Novartis 5 figured it out that the answer came out, 6 right?</p> <p>7 MR. GALLAGHER: Objection. 8 Mischaracterizes testimony, and lacks 9 foundation. 10 You can answer. 11 A. Let me give you a -- I try to 12 give you a full answer, okay, part by part or 13 little by little. Okay? 14 The FDA statement, the first 15 one says, "Your response states that NDMA was 16 difficult to detect," okay? 17 So this was -- FDA's basically 18 repeating our language at the time, right? 19 Okay. If you look at, you know, Dr. Janet 20 Woodcock's statement, okay, she released 21 during January -- in January 2019, right 22 after, you know, this event came out, in 23 that, you know, statement, you know, there is 24 one sentence, something like, you know, it</p> |
| <p style="text-align: right;">Page 271</p> <p>1 I already answered that question multiple 2 times.</p> <p>3 Q. Well, let's look right in the 4 middle of the page where we just went through 5 this -- well, rephrase.</p> <p>6 Looking now at the middle of 7 this page in Exhibit 213, the FDA Warning 8 Letter of November 2018, it says, "Your 9 response states that NDMA was difficult to 10 detect. However, if you had investigated 11 further, you may have found indicators in 12 your residual solvent chromatograms alerting 13 you to the presence of NDMA."</p> <p>14 And then they point out, the 15 FDA says, "For example, you told our 16 investigators you were aware of a peak that 17 eluted after the toluene peak in valsartan 18 API residual solvent chromatograms where the 19 presence of NDMA was suspected to elute."</p> <p>20 So -- and then they say -- just 21 to be clear, they say, "At the time of 22 testing, you considered this unidentified 23 peak to be noise and investigated no 24 further." So I want to stop there.</p> | <p style="text-align: right;">Page 273</p> <p>1 said, the -- like, the property of NDMA made 2 it difficult to be detected by, like, a 3 normal or routine analytical test method. 4 Something like that. Okay. 5 So, you know, so basically 6 combining everything that I told you, you 7 know, with the GC-FID method, okay, you know, 8 again, you know, you know, this peak, right, 9 that I -- you know, that we told, you know, 10 this particular inspector, right, the peak 11 eluting after the toluene, you know, as I 12 said, this is not NDMA. 13 NDMA is just -- yeah, just at 14 the noise level, you know. As I said, at the 15 NDMA in the real sample, you know, it was 16 just among the smallest, you know, peaks, 17 okay. So it's -- you know, it's just that -- 18 you know, at that kind of level. 19 So that's -- you know, that's 20 exactly what happened. I mean, all right. 21 So you know, basically, again, as I 22 indicated, you know, the nature of the GC-FID 23 method is not designed to detect, you know, 24 such low level peaks. Its purpose is to</p> |

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| <p>1 monitor, you know, the residual solvents 2 that, you know, that one particular process 3 utilized, you know, in that process. 4 So from that perspective, you 5 know, that GC-FID residual solvent method is 6 still, you know, suitable. Okay. I think 7 that, you know, we're still utilizing this 8 residual solvent method, okay, to release the 9 valsartan API or drug substances, okay, to, 10 you know, European, you know, customers, 11 after we modify, you know, the process of 12 valsartan API.</p> <p>13 BY MR. SLATER:</p> <p>14 Q. ZHP modified its SOPs so that 15 following this revelation to the public about 16 the NDMA, now you're required to use GC-MS to 17 identify unknown peaks as a matter of course, 18 right?</p> <p>19 MR. GALLAGHER: Objection to 20 form.</p> <p>21 A. Well --</p> <p>22 BY MR. SLATER:</p> <p>23 Q. That's what the SOP says now, 24 right?</p> | <p>Page 274</p> <p>1 Right now, you know, I can tell 2 you it's way below the detection limit of the 3 original detection limit that we established, 4 you know, after these events, because, as I 5 mentioned to you in the very beginning, FDA, 6 you know, the original position was it should 7 be absent, right?</p> <p>8 So based upon FDA's, you know, 9 published analytical method for NDMA as well 10 as for NDEA, and for NDMA the FDA's, you 11 know, limit of quantitation is 5 ppb, okay. 12 For NDEA the limit was 1 ppb, right? So our 13 valsartan now is able to meet both, you know, 14 you know, you know, requirement.</p> <p>15 Although, as I said, you know, 16 you know, FDA has basically retreated, you 17 know, from their original position, right? 18 Now it's being allowed, you know, you know, 19 you know, for example, like for NDMA, now 20 they allow, you know, 96 nanogram per day, 21 which would translate into 300 ppb's, okay?</p> <p>22 And so our product, our, you 23 know, valsartan utilized this newly, you 24 know, developed or modified process. Okay.</p> |
| <p>1 A. Our SOP -- yeah, because of -- 2 yeah, based upon -- yeah, based upon the 3 investigation, or the outcome, you know, of 4 the investigation, our SOP now requires any 5 unknown peaks, okay, with a signal-to-noise 6 greater than 10 would be investigated, okay? 7 And both FDA and also regulatory agency, they 8 agree with this threshold, okay? So that's 9 number one, all right?</p> <p>10 And since then we have done 11 tremendous, you know, you know, amount of 12 testing utilizing GC-MS, even GC-MS/MS, 13 right, and we have done so many tests. And 14 so far we were not able to find another 15 nitrosamine, you know, you know, you know, 16 with this approach. Okay?</p> <p>17 Q. Well, if you're talking about 18 batching going forward, you were required to 19 optimize the process so you wouldn't form 20 nitrosamines, right?</p> <p>21 A. Nitrosamine could still be 22 present, okay, based upon the nature of the 23 chemistry. Okay? It all depends upon how 24 much, right?</p> | <p>Page 275</p> <p>1 We are able to generate, you know, you know, 2 valsartan way below, you know, the 300 ppb, 3 okay? So it's below, you know, you know, 5 4 ppb. So it's 60 times lower, you know, for 5 the method, the detection limit.</p> <p>6 MR. SLATER: Let's look at 7 page 4 of the warning letter, Cheryll, 8 if you're still there. Thank you. 9 Okay. Could you scroll up a little 10 bit more, please?</p> <p>11 Q. Okay. Under number 2, the 12 second paragraph, starting with the second 13 sentence, the FDA advised you, "You are 14 responsible for developing and using suitable 15 methods to detect impurities when developing, 16 and making changes to your manufacturing 17 processes. If new or higher levels of 18 impurities are detected, you should fully 19 evaluate the impurities and take action to 20 ensure the drug is safe for patients."</p> <p>21 My first question is, do you 22 see what I just read?</p> <p>23 A. Let's see. Which paragraph? 24 I'm sorry.</p> |

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| <p>1 Q. Second paragraph under 2 number 2.</p> <p>3 A. Second paragraph. Oh, starting 4 with "You also failed to," right?</p> <p>5 Q. Yes.</p> <p>6 A. Okay. Let me read through. 7 I'm sorry. It's getting a little bit too 8 long. You also... okay.</p> <p>9 (Witness reviewing document.)</p> <p>10 A. So I don't know, you know, 11 whether this is specifically referenced here. 12 If here, you know, FDA specifically, you 13 know, referring to NDMA issue, I think this 14 is in a statement, you know, after the fact.</p> <p>15 Q. This is my question. You saw 16 what I just read, right?</p> <p>17 A. Yeah. I read through the 18 second paragraph, yes.</p> <p>19 Q. You would agree with me that 20 that is a correct statement of ZHP's 21 responsibilities under good manufacturing 22 practices, right?</p> <p>23 A. See, the precondition here is 24 you need to know, or you have that knowledge,</p> | <p>Page 278</p> <p>1 A. As I said, if it's a general 2 statement, right. You know, for any -- like 3 a regular, you know, impurity that really 4 being, you know, appropriately detected like 5 it was any -- like, you know, what we called 6 a related substance method, you know, you 7 know, or whether, you know, we will do the 8 impurity, you know, identifications. I 9 mean...</p> <p>10 Q. ZHP was required to fully 11 evaluate the impurities and take action to 12 ensure that the valsartan was safe for 13 patients. That you'll agree with, right?</p> <p>14 A. Again, you know, if we knew at 15 the time, you know, yeah, we will do that, 16 yes.</p> <p>17 Q. Well -- rephrase.</p> <p>18 MR. SLATER: You know what? 19 Now we can break.</p> <p>20 MR. GALLAGHER: Okay. 21 MR. SLATER: Off the record. 22 THE VIDEOGRAPHER: The time 23 right now is 1:07 p.m. We're now off 24 the record.</p> |
| <p>1 at the time of the process change. So that 2 process change was made somewhere around 2011 3 to 2012.</p> <p>4 Q. The point is, you would agree 5 that ZHP, like any drug manufacturer, is 6 responsible to use -- develop and use 7 "suitable methods to detect impurities when 8 developing, and making changes to, 9 manufacturing processes."</p> <p>10 You agree with that statement, 11 right?</p> <p>12 A. If during that period, right, 13 during that initial development time, if 14 someone, you know, involved in -- you know, 15 in that, you know, development of that 16 process, yeah, if they knew, they would 17 develop a suitable method.</p> <p>18 Q. And you also agree that "If new 19 or higher levels of impurities are detected, 20 you should fully evaluate the impurities and 21 take action to ensure the drug is safe for 22 patients"?</p> <p>23 You agree with that statement, 24 right?</p> | <p>Page 279</p> <p>1 (Whereupon, the deposition was 2 adjourned.)</p> <p>3</p> <p>4</p> <p>5</p> <p>6</p> <p>7</p> <p>8</p> <p>9</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> |

Page 282

Page 284

1 CERTIFICATE
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3 J. MAUREEN O'CONNOR
4 POLLARD, Registered Diplomate
5 Reporter, Realtime Systems
6 Administrator, and Certified Shorthand
7 Reporter, do hereby certify that prior
8 to the commencement of the
examination, MIN LI, Ph.D., was remotely
9 duly identified and sworn by me to
10 testify to the truth, the whole truth,
11 and nothing but the truth.

12 I DO FURTHER CERTIFY that
the foregoing is a verbatim transcript
of the testimony as taken
stenographically by and before me at
the time, place, and on the date
hereinbefore set forth, to the best of
my ability.

13 I DO FURTHER CERTIFY that
I am neither a relative nor employee
nor attorney nor counsel of any of the
parties to this action, and that I am
neither a relative nor employee of
such attorney or counsel, and that I
am not financially interested in the
action.

19 MAUREEN O'CONNOR POLLARD
NCRA Registered Diplomate Reporter
Realtime Systems Administrator
Certified Shorthand Reporter
Notary Public

22 Dated: April 20, 2021

1 INSTRUCTIONS TO WITNESS
2

3 Please read your deposition over
carefully and make any necessary corrections.
5 You should state the reason in the
6 appropriate space on the errata sheet for any
7 corrections that are made.

8 After doing so, please sign the
9 errata sheet and date it. It will be
10 attached to your deposition.

11 It is imperative that you return
the original errata sheet to the deposing
13 attorney within thirty (30) days of receipt
14 of the deposition transcript by you. If you
15 fail to do so, the deposition transcript may
16 be deemed to be accurate and may be used in
17 court.

1 -----
2 ER R A T A
3 -----
4 PAGE LINE CHANGE
5 REASON: _____
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Page 283

Page 285

1 ACKNOWLEDGMENT OF DEPONENT
2

3 I, _____, do
4 Hereby certify that I have read the foregoing
5 pages, and that the same is a correct
6 transcription of the answers given by me to
7 the questions therein propounded, except for
8 the corrections or changes in form or
9 substance, if any, noted in the attached
10 Errata Sheet.

11 Min Li, Ph.D. Date _____

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17 Subscribed and sworn
To before me this
18 _____ day of _____, 20_____.
19
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My commission expires: _____

21 Notary Public
22
23
24

Page 286

1 LAWYER'S NOTES

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